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IMPACT ASSESSMENT

Accompanying the document

Proposal for REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

establishing a Union certification system for aviation security screening equipment

{COM(2016) 491 final}
{SWD(2016) 259 final}

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1. INTRODUCTION

In the absence of any EU-wide rules on certification, Member States have adopted different approaches when it comes to approving and/or/certifying aviation security screening equipment before placing it on the market. The purpose of this impact assessment is to identify the consequences this situation has and assess the possible policy options to address them.

1.1. Policy Context

The Commission Communication *"Security Industrial Policy Action Plan for an innovative and competitive Security Industry* (COM (2012) 417)" [1] announced under action 2: *"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***[2]*; and one to establish an EU harmonised certification system for alarm systems. The objective is to achieve mutual recognition of certification systems.***"**

Increasing the competitiveness of EU companies by overcoming the fragmentation of the EU security markets is a priority for the European Commission as outlined by President Juncker in his Political Guidelines:

"Our internal market is Europe's best asset in times of increasing globalisation. I therefore want the next Commission to build on the strength of our single market and to fully exploit its potential in all its dimensions. We need to complete the internal market in products and services and make it the launch pad for our companies and industry to thrive in the global economy, […]"("A Deeper and Fairer Internal Market with a Strengthened Industrial Base").

The **European Agenda on Security**[3] also emphasised the need for a *"competitive EU security industry" which "can also contribute to the EU's autonomy in meeting security needs. The EU has encouraged the development of innovative security solutions, for example through standards and common certificates".* In that context, the Commission reiterated its will to consider further action, such as on alarm systems and airport screening equipment[4], to remove barriers to the Single Market and to enhance the competitiveness of the EU security industry in export markets.

The aviation security sector

Aviation screening equipment relate to the equipment used for the screening of persons, cabin baggage, hold baggage, supplies, cargo and mail. Aviation security screening equipment means equipment subject to current legislation (Regulation (EC) No 300/2008), i.e. currently walk-through metal detection equipment (WTMD), security scanners (SSc) which do not use

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0417:FIN:EN:PDF

[2] The Security Industrial Policy Action Plan refers to airport screening equipment while this Impact Assessment refers to aviation screening equipment. The terminology was changed in the drafting process to "aviation" as this encompasses the whole aviation transport chain, while "airport" would leave out aspects related to cargo.

[3] COM(2015) 185 final

[4] The European Agenda on Security refers to airport screening equipment while this Impact Assessment refers to aviation screening equipment. The terminology was changed in the drafting process to "aviation" as this encompasses the whole aviation transport chain, while "airport" would leave out aspects related to cargo.

ionising radiation, cabin baggage x-ray imaging equipment (CBS), liquid explosives detection systems (LEDS), explosives detection equipment for carry on and divested items (EDS-C), explosive detection systems for hold luggage (EDS), and explosive trace detection equipment (ETD).

Screening equipment in the aviation security sector represents a considerable market, with an annual global turnover of 14 billion Euros, 4.2 billon 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. For illustration, during the next 10 years the market for aviation security in China is expected to grow by 140%.[5]

The supply of screening equipment for the aviation transport sector is concentrated among a few international players, coming mainly from the US and the EU Member States. These include Smiths Detection, Rapiscan and L3 which are large multinational companies based both in the EU and in the US and companies such as Morpho (Safran), CEIA and SMEs such as Gilardoni which are EU based.

Other US companies, such as Bruker, Analogic, Sellex and FLIR, have produced aviation security screening equipment but to date have limited market penetration outside the US. In terms of other international competitors, the only significant companies in this sector are the Chinese company Nuctech and the Canadian company OptoSecurity, although there are other Chinese, Israeli, Japanese, Korean and Russian manufacturers of aviation security screening equipment who, to date, have limited or no penetration of this sector in Europe.

Looking below the first-tier of what are essentially global players, the European industry in this sector appears somewhat fragmented. The remainder of the sector is characterised by EU companies of relatively limited size such as Kromek, Cobalt Light Systems and System Two, focussed on the development of specific technologies and/or offering specialised or niche products to the market such as liquid screening technologies. The limitations that come from their size means they have limited capability to compete with the major players, with whom they often need to develop partnerships to have access to broader market segments.

It is difficult to quantitatively assess the competitive position of EU suppliers of aviation security screening equipment. Information on the global market position of EU suppliers is not readily available and estimates, where they exist, are subject to wide differences. Even for the aviation security market as a whole, estimates differ substantially across sources. Moreover, aviation security screening equipment is not identifiable from existing product classification used for the collection of international trade data. This implies that there are no export and import data at country level for the aviation security screening equipment segment. Equally for the large multinationals it is hard to distinguish the data for sales of aviation security screening equipment from their other activities.

To provide a quantitative impression of the competitive position of EU suppliers, this Impact Assessment makes use of the annual reports for some of the main players identified above. Insofar as data are available the annual reports give information about sales revenues by geographic market area. Table 2 shows the share of revenues by main market for six of the main companies active in the aviation screening sector. The last line reports estimated total revenues in 2012 in million Euros, based on the reported information on the share of security and detection in total revenues.[6]

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[5] See: http://ec.europa.eu/enterprise/policies/security/documents/index_en.htm

The major American and European companies are competing with each other at a global level, although subject to the specific peculiarities and preferences within the main Western and other international markets.

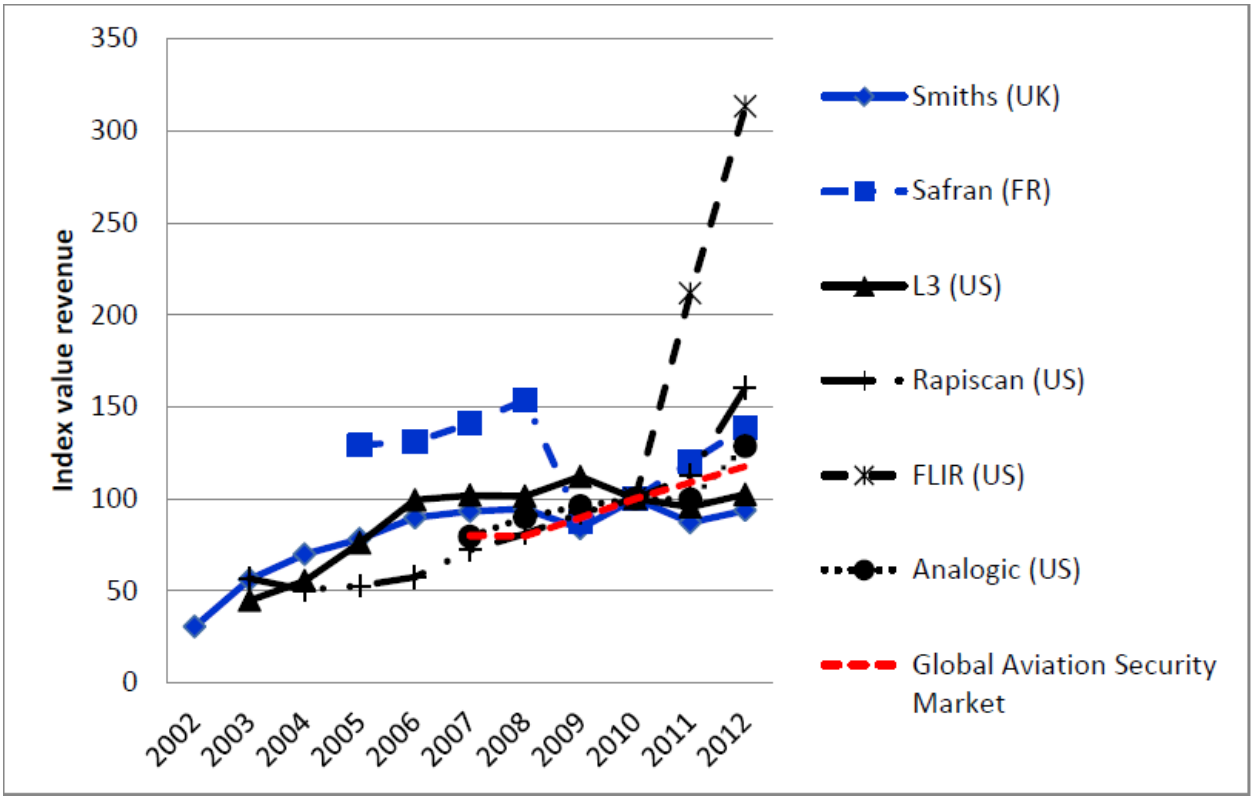
Table 1: Revenues of main companies in aviation screening equipment by geographical market area (2012, percentage of total revenue)

	Smiths (UK)	Safran (FR)	L3 (US)	Rapiscan (US)	FLIR (US)	Analogic (US)
Europe	26%	46%	6%	19%	24%	24%
Americas				68%		
North America	50%	30%	84%		51%	39%
Asia	7%	16%	1%	12%	.	16%
Oceania	.	.	1%	.	.	.
Other	17%	8%	8%	0%	25%	21%
Total revenues (million euro)	**635**	**1492**	**256**	**302**	**66**	**48**

Source: annual reports; Ecorys. Notes: Analogic's figures for Europe include Germany, the Netherlands and Denmark, and Asia refers to Japan only. "Other" includes the rest of Europe, Canada and China for example. The Netherlands accounts for 12% of revenue, but most likely this is mostly in medical appliances. In security, this share is likely an overestimate. The figures for Rapiscan refer to the Americas, including the North American and Latin American markets.

Though still in a strong position, there is some evidence to suggest that main EU suppliers have lost some ground in terms of market shares over time since about 2007

Table 2: Development of total revenue for main companies in aviation screening equipment over time (index; 2010=100)



Source: annual reports; HSRC (2008); Ecorys.

A more detailed assessment of the competitiveness of the EU manufacturers can be found under point "3.4. The external dimension".

2. PROBLEM DEFINITION

2.1. The lack of an internal market for aviation security equipment

In absence of a common legally binding procedure for the certification of aviation security screening equipment in the EU Member States, there is no single, legally binding EU-wide mechanism by which this equipment is approved and the methods by which Member States certify equipment diverge.[7] **This fragmentation has effectively hindered the creation of a true internal market for aviation screening equipment in the EU.** This causes inefficiencies and impedes **the competitiveness of European manufacturers** of aviation security screening equipment.

There is an applicable EU legislation[8] on the technical specifications and performance requirements for aviation security screening equipment used at EU airports. This legislation is based on performance standards developed by the Commission, which are continuously adapted to the evolving threat scenarios and risk assessments. These standards and the two related regulations are not being addressed by this initiative as they are already applied across the EU. These standards are classified and only made available to those (persons, companies, organisations etc.) which have an adequate security clearance as well as a valid justification ("need to know basis"). This aspect has an impact on the choice of policy options described under section 4 "Policy Options".

This legislation, however, **is not accompanied by a legally binding EU-wide conformity assessment[9] 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 Member State is free to recognise this certification, to require that the equipment is tested again to verify it meets the requirements prescribed by EU legislation, or to refuse its use in their territory. In any case, this second Member State is obliged to issue its own certification, which is not based on the automatic recognition of the initially certifying Member State.

However there is an exception. Within Regulation (EU) 185/2010, point 12.7.3, there is the provision that for liquid explosive detection systems if equipment is approved by or on behalf of one appropriate authority of a Member State, it shall be recognised by other Member States as meeting the EU standards. This does not however mean that there is an EU system in place based on common testing procedures. Nor does it mean that the Member States all use the same procedures. Every Member State can set up its own methodologies if it wishes. So far, no case of mutual recognition based on the provision of the Regulation 185/2010 has been recorded.

Member States through ECAC[10], and 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. In 2008 ECAC put in place a

[7] An overview of the divergent approaches on certification procedures for aviation security screening equipment can be found in table **4**.

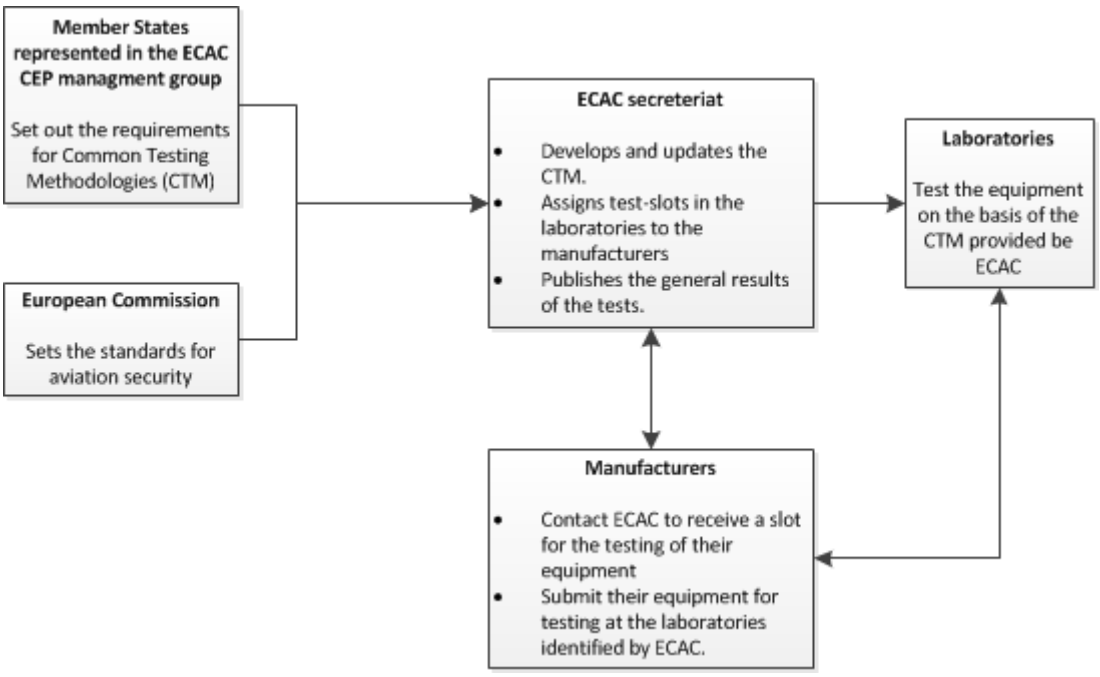
[8] The two relevant regulations are: (EC) No 300/2008 and (EC) 185/2010, Commission Decision 774/2010.

[9] Definition from Regulation (EC) No 765/2008: 'conformity assessment' shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled.

[10] European Civil Aviation Conference consisting of 44 European countries (including 28 EU Member States), https://www.ecac-ceac.org/

framework for the evaluation of security equipment used in the aviation sector (ECAC Common Evaluation Process (CEP)).

Schematic overview of the repartition of roles in the aviation screening equipment sector



Today ECAC provides a common method of testing for many Member States and tests an increasing proportion of the aviation security screening equipment described in the EU regulation. The ECAC CEP applies to Explosives Detection Systems (EDS), Liquid Explosive Detection Systems (LEDS), Explosive Trace Detection (ETD) and Security Scanners (SSc). In 2015 this will be extended to at least Cargo Metal Detection Equipment (MDE) and EDS for cabin baggage (EDS-C). The ECAC Common Testing Methodologies (CTM's) are developed by the ECAC Technical Task Force (TTF) and endorsed by all 44 ECAC Member States (which includes all 28 Member States).

It should be noted that several of the problems related to ECAC identified during consultations have been improved or resolved. The passages of the public consultation on these aspects have therefore been disregarded for the drafting of this Impact Assessment:

- The overall number of laboratories for aviation screening equipment has increased as well as their testing capacities. Manufacturers can now freely choose the laboratory at which they want to have their equipment tested.
- The bottlenecks at the laboratories for testing slots for aviation screening equipment have been reduced.
- The duplication of testing for aviation screening equipment has been reduced.
- The speed at which the test results are transmitted by the laboratories has been improved.

However, approval (certification) of equipment remains at national level and does not preclude national authorities from subjecting screening equipment to their own national testing and validation procedures. The ECAC CEP publishes test results but does not issue

certifications. Equally the CTMs are not legally binding, nor do they prevent a Member State from requiring additional or different tests. The problem of a lack of legal certainty on the certification process therefore still persists.

In the absence of any EU-wide rules on certification, Member States have adopted different approaches when it comes to approving and/or/certifying aviation security screening equipment before placing it on the market. These divergent approaches have been mapped in a survey launched by the Joint Research Centre in autumn 2012, which asked for information regarding the certificate requested in each Member State for aviation security screening equipment to be eligible for a tender. The survey clearly shows that no single certification system is used across the whole EU. While some base themselves on the ECAC system described above, others rely on the US certification scheme, the approval of other Member States or, in one case, have no requirements at all. A more detailed overview of these divergent approaches can be found in the study of the JRC.

Table 4: Overview of the diverging approaches on certification procedures for aviation screening equipment in EU and EFTA Member States

Responses to the question: *'What approval(s)/certificate(s)/information are requested for an eligible tender concerning performance requirements and conformity to Regulation?'* Note that respondents selected more than one option. The share of responses is calculated against the total number of responses to the questionnaire (27).

Reply	Number of responses	Share of responses	Share of EU/EFTA passenger flow
Approved/certified by a dedicated entity in Member State	7	25.9%	55.1%
Passed ECAC CEP	20	74.1%	67.7%
'Complies with EU Regulation'	20	74.1%	62.5%
Approved/certified by other Member State(s)	12	44.4%	28.5%
Used by other Member State(s)	3	11.1%	3.3%
TSA approved[11]	5	18.5%	9.0%
None	1	3.7%	2.7%
Other (please specify)	0	0%	0%

The studies and consultations mentioned above concluded that the lack of a harmonised certification system affects the efficiency of the certification process for aviation security screening equipment in the EU.

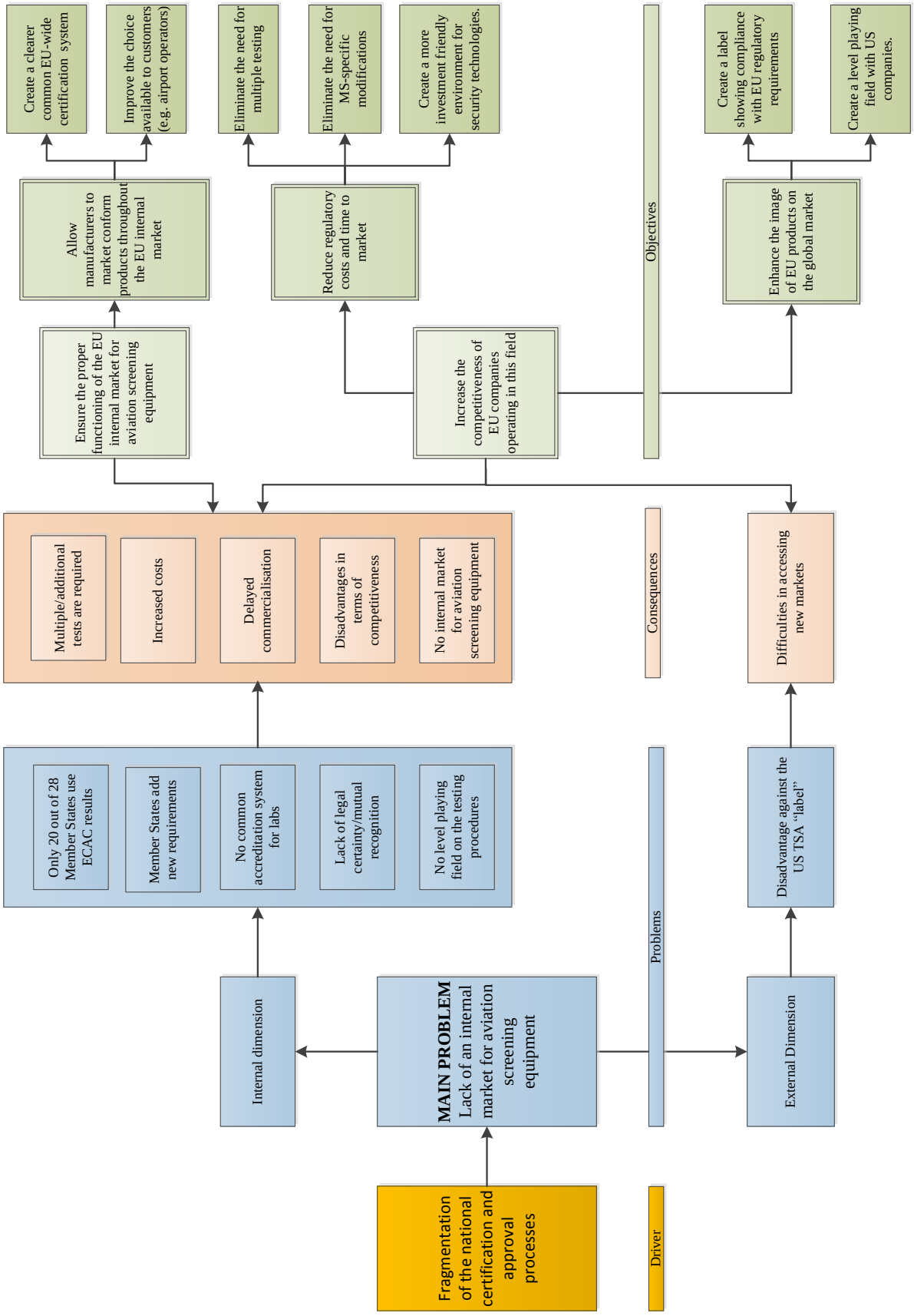
In the context of the **public consultation**, on the question: "What effect do you think the current situation where there is no harmonised certification system for aviation security equipment has had on the efficiency of the certification process?" 78,38% of the respondents answered either with "Very negative effect" (48,65%) or "Negative effect" (29,73%).

Thus, in the absence of a common overall EU framework for aviation security, differences in national approaches and requirements persist. These differences can be particularly pronounced when they concern the evaluation and introduction of new security technologies and solutions. This can result in situations where equipment may be certified and approved in

[11] "TSA approved" means that a technology has been successfully certified by the US Transportation Security Administration

one Member State but not in another. The negative effects resulting from the absence of a harmonised certification system for aviation security equipment can be divided in two categories: (i) effects on the internal dimension, and (ii) effects on the external dimension.

Problem tree and objectives



It should be noted that there are a number of substantial differences between aviation and other screening equipment (e.g. used for access to buildings) in terms of their certification and placing on the market. The existing aviation security legislation is the only one establishing a list of threats whose detection is mandatory. Other sectors' screening equipment has no mandatory technical standards. The purchase of other sectors' screening equipment is not done via public procurement but rather via direct negotiation buyer-manufacturer/retailer.

2.2. The internal dimension of the market fragmentation for aviation screening equipment

As mentioned there is no EU-wide legally binding system by which aviation security screening equipment can be certified, which has **prevented the creation of an internal market for aviation screening equipment.** Furthermore the ECAC CEP system itself has the potential for improvement. All these issues are discussed in this section.

Lack of legal certainty and mutual recognition

The ECAC CEP, which is close to a common certification system, is not legally binding upon Member States. They are not obliged to accept the results of the ECAC CEP nor are they equivalent to an acceptance by all the Member States. Test centres are approved by ECAC and national authorities to execute the tests, but are not recognised by the Commission as is the case with Notified Bodies in the Single Market Legislation[12].

Thus there is no guarantee that a piece of equipment that has passed the ECAC CEP will be accepted as such by the appropriate authority of a given country (i.e. ECAC Member State) where the manufacturer of that equipment would like to market it. The ECAC CEP is merely a common system for testing equipment and reporting the outcome of the tests to the ECAC Member States. Manufacturers are therefore left with the risk of having to re-test or even modify their product for every Member State in which they want to commercialise it.

This has already led to situations where equipment that successfully passed the ECAC CEP was not accepted in the Member State in which the manufacturer wanted to market it. This increases their development costs as well as their time to market. Given the limited resources available to an SME, this is a proportionally greater problem for it than for a larger company.

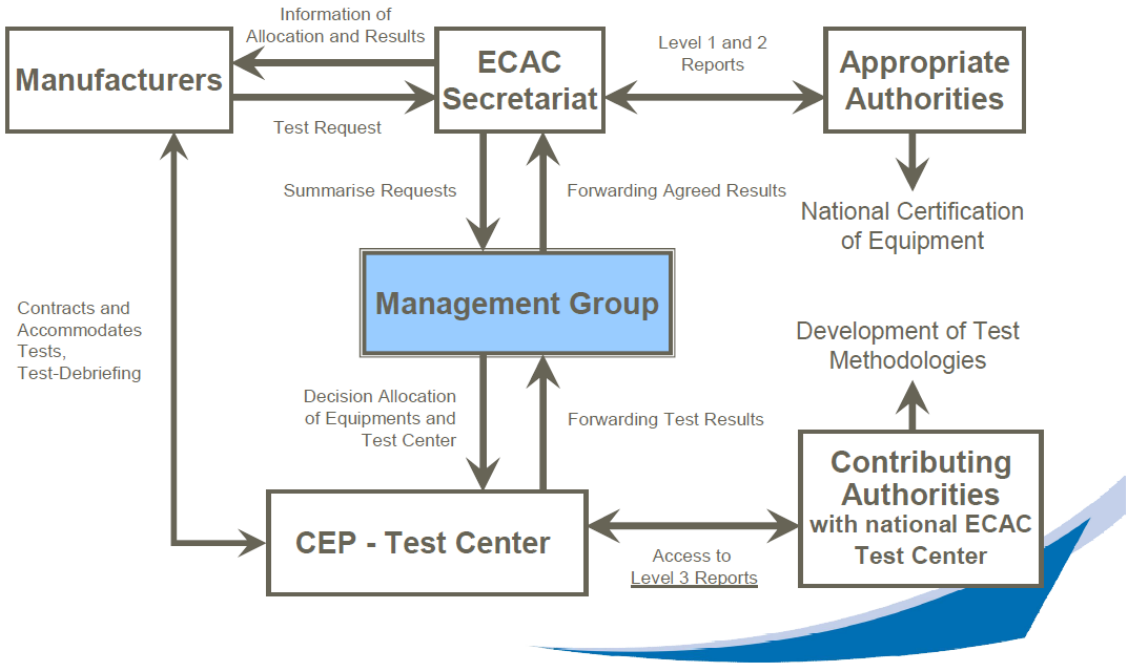
This negatively affects both the manufacturers and the end-users of the equipment. The manufacturer has to face new development/modification requirements that **increase the commercialisation costs** as well as the **time to market**, which has a negative impact on both industry and end-users, who have a limited choice of purchasable equipment.[13]

This assessment has also been confirmed by the respondents of the **public consultation**[14]. On the question: "What effect do you think the current situation where there is no harmonised certification system for aviation security equipment has had on the Legal certainty?" 78,38% of the respondents answered either with "Very negative effect" (45,95%) or "Negative effect" (32,43%).

Regulatory dimension – the ECAC testing process

Table 3: Organisation of the ECAC-CEP

[12] Reference:
[13] See SER3CO study
[14] See annex 2



Source: German Federal Police Department / Federal Police Technology Centre

Manufacturers have noted inconsistencies in how the tests are applied and the quality of testing as a result, in some instances this has led to the same equipment failing in one test centre but passing in another resulting in extra time and costs for the manufacturer to obtain a positive result.

Once an ECAC testing laboratory has completed its assessment of a piece of equipment a test report is sent to the ECAC management group. The reports are then sent to the ECAC secretariat for the publication of those that are successful. Within this system the results of ECAC testing can be published up to three months after a laboratory has completed testing. Member States then add additional time for their individual certification processes. The ECAC secretariat is also responsible for the assigning of tests to testing laboratories, leading to similar delays at the start of their assessment process.

It should be noted that there has been progress on the efficiency of the ECAC CEP system over the last years. Member States have extended their cooperation in ECAC which has led to an improvement of the testing procedures as well as harmonization of quality. This did however not improve the lack of mutual recognition or, the lack of legal certainty.

2.3. The external dimension

The fragmentation of the internal market **has also a negative impact on the competitiveness of the European industry in comparison to their global counterparts**. EU companies competing on world markets can only cite as a reference the results of the voluntary ECAC CEP that offers no legal certainty or the certification by those EU Member States who have provided one. In comparison, US companies can rely on a globally renowned and recognised approval by the US Transportation Security Administration (TSA). US companies can thus rely on a clearly recognisable label which ensures a better access to third countries markets.

Several industry representatives stated that this gave US companies a strong competitive advantage in comparison to EU based companies when competing in third countries (e.g. Brazil). Stakeholder consultations have shown that the likelihood of a technology which passed the ECAC CEP system being chosen in a tender is considerably hampered by its

uncertain legal status and the lack of an EU-wide application.[15]A US company can state during a sales pitch that their product has successfully passed the tests of the globally known TSA system. An EU company can only state that their technology has been tested in a system, which is not fully recognised by EU Member States. EU products thus often appear less credible than those of their US competitors.

Illustrative example taken from the workshop discussion

A specific example was given by an industry representative who stated that, while competing in a tender against a US company for a contract in Venezuela, he was negatively affected by the legal uncertainty of the ECAC system. Being non-binding, the value of a testing system which is not mandatory across the EU suffers a great deal against the well-known and legally binding certification of the TSA. The US competitor used this difference during the tendering process as a sales argument and successfully discredited the European manufacturer.

The assessment of these disadvantages was also largely supported by the public consultation. On the question "What effect do you think the current situation where there is no harmonised certification system for aviation security equipment has had on competition with US competitors" 72,97% of the respondents answered either with "Very negative effect" (21,62%) or "Negative effect" (51,35%).

During the interviews held in the context of the SER3CO study manufacturers stated that their experience is that manufacturers that have a product that is certified by the Transportation Security Administration, are using this "TSA stamp" in their sales on third markets, especially emerging markets, as a selling argument. This picture is confirmed in some of the country studies such as South Korea.

The TSA certification system

The loss in market share in emerging markets and in mature markets to these US suppliers may be related to the general framework conditions. In particular, the regulatory environment in the US is more conducive to development and certification of aviation screening equipment.

On top of the general regulatory environment, the adoption of a harmonised US certification systems administered by TSA in 2007 provided marketing advantage to US suppliers. Clients in various emerging markets require equipment to have a US certificate as proof of its performance.

Both studies and consultations assessed that EU companies are among the technological frontrunners in the field of aviation security. There are no indications that companies are lagging behind their US counterparts in terms of technology. It should be noted that the European Commission invested considerably in R&D in this sector through the Security Theme of the Seventh Framework programme for Research and Development (FP7).[16]

2.4. Outcome of the public consultation

The public consultation provided a series of concrete answers to the initial assessments of the Commission on the problems that affect the certification system of aviation screening equipment. A clear distinction can be made between the widely acknowledged problems which should be addressed by the Commission and the problems which had only a very marginal support and could be discarded.

[15] See SER3CO study

[16] The Commission financed 14 research projects in this area, worth 91 million Euros in EU contribution.

The central problems identified by the respondents concern mainly the negative effects due to the fragmented regulatory framework of the certification system on:

1. The commercialisation of aviation security screening equipment (i.e. research and development costs, the legal certainty and the efficiency of the certification process and the time to market of equipment); and

2. The external dimension (i.e. acceptance of performance by third countries and competition with third countries such as the US).

It should be underlined that these assessments were made by the majority of stakeholders be they SME, large industry, test laboratories or business associations. The only group of respondents which expressed some reservations were the representatives from national administrations.

- Issues like the use of airport space, the training of personnel, passenger and staff security and the passenger flow were deemed to be largely irrelevant by the respondents for the scope of this initiative. As an example, on the question regarding the use of airport space, 14% of the respondents answered either with very negative effect or negative effect. Nearly 80% of the respondents did not see any effect, **including all airport operators**. The need for the Commission to act on these aspects thus seems secondary.

2.5. Underlying drivers of the problem

The main underlying driver is the current fragmentation of the national certification and approval processes, which leads to the internal market problem explained above and its negative consequences for EU aviation security industry.

2.6. Who is affected, in what ways and to what extent?

The lack of a common legally binding certification system for aviation security screening equipment negatively affects the following stakeholder groups: national authorities responsible for aviation security, equipment manufacturers (ranging from large-scale system integrators to small and medium companies and suppliers of components), and airport operators. An overview of the value chain for aviation screening equipment can be found under annex 5.

Appropriate authorities

The Appropriate Authorities in the Member States are currently facing some uncertainty on the legal character and the quality of the testing in the various laboratories. The ECAC CEP system is not based on a legally binding legislation, the results of the testing procedures do therefore not give the authorities the same certainties on compliance that legislation would provide. The Appropriate Authorities currently have to analyse the results of ECAC CEP and assess if extra testing is required, in case they have more stringent measures (measures specifying requirements above the EU baseline) in place which they have notified to the European Commission.

Industry/ Equipment manufacturers

The lack of efficiency has a series of negative consequences for the competitiveness of the European industry. The delays due to the lack of legal certainty, the testing process, and the certification process negatively affect their time to market and increase their production costs.

The lack of a unique "EU certified brand" hampers their position in competitions with US manufacturers.

Small and medium enterprises are particularly affected by these problems as they often have more limited resources. Any increase in development costs or timelines increases the barriers to entry to a given market. Any divergence in national requirements makes it more difficult for them to adapt their technologies due to the added burden this puts on their resource and finances.

Airport and air transport hub operators

Any delay to the development of new technology or increase in the cost of equipment also negatively affects airport operators. Airport operators also need to ensure their equipment meets the requirements for aviation security. An EU certification system would help EU airports confidently identify equipment, especially where the information is not readily available at a Member State level.

Where new equipment is required by legislation airports are particularly dependent on a timely commercialisation of new technologies to fulfil such security requirements. Any delay in certification can harm the ability of the airport to fulfil these obligations. The current lack of efficiency of the certification has led to situations where airport operators had only a limited (if any) choice of products available in the prescribed legal timeframe which meets their demands. This is not only a concern in terms of aviation security but also leads to a temporary lack of competition among the manufacturers as delays in testing and certification can prevent equipment from reaching the market in time.

2.7. Evolution of the problem

Air transport is expected to grow strongly for the foreseeable future at the same time as transport security concerns are growing. As a consequence, more security screenings need to be carried out and more aviation security screening equipment needs to be installed and operated.

Estimates by the International Civil Aviation Organisation (ICAO) predict that International air traffic is envisioned to grow at a rate of 5.3 per cent per annum for passenger-kilometres and 6.9 per cent per annum for freight tonne-kilometres over the next years. The International Air Transport Association (IATA) forecasts that by 2016, China will have 415 million fliers annually, second only to the U.S. in volume of domestic passengers. The current Five Year Plan of the People's Republic of China calls for the construction of 55 new airports until 2015.[17]

This presents business opportunities for manufacturers of aviation security screening equipment. EU companies are still among market leaders and benefit from a relative technological advantage and high quality manufacturing compared to some of the emerging countries in Asia. Yet their past relative performance compared to US competitors and forecasts made by EU industry on the future competitiveness indicate that EU manufacturers are losing competitiveness.

The main competitors are US companies, who benefit from a harmonised legal framework and a worldwide /widely recognised certification system. This gives them not only a strong home market basis but also the benefit of a clearly recognised and distinguishable US brand,

[17] See: http://www.eu-china.net/web/cms/upload/pdf/materialien/11-06-30_12th-Five-Year-Plan-China-english.pdf

which has proven to be a highly valuable advantage compared to EU companies in terms of international competition.

At the same time, Asian countries are closing the technological gap that separates them from EU companies at an increasing rate, while also benefitting from a production cost advantage in comparison to EU firms. This effectively gives Asian companies a competitive advantage against EU manufacturers, particularly in third country markets.

Without a policy initiative to support the competitiveness of the European manufacturers the market shares of these companies on the global market are bound to decrease constantly over the next years.

2.8. EU right to act

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, namely, the proper functioning of the internal market.

The current fragmentation of the certification systems for aviation security screening equipment in the EU is a result of the lack of a common legally binding certification process among the Member States. This hindered the creation of an internal market for aviation security screening equipment and hampered the competitiveness of the European Security Industry. There are no indications that Member States are planning to take any measures to reduce this fragmentation.

This is also confirmed by the results of the study of the JRC. One of the questions to the Member States in this study concerned the sharing of information with other EU Member States and/or ECAC on the results of the certifications or approvals for aviation security screening equipment among the Member States. The exchange of this information would be an essential component/initial step of any EU-wide certification system. As the table below shows, none of the 18 Member States consulted in this study replied that they share this information.

Table 6: Number of the Member States which issue certifications and share the results of the process with other Member States and/or ECAC

Responses from 18 countries issuing certificates or approvals to the question: 'Are other EU Member States and/or ECAC informed about issued approvals/certification procedure?'			
Reply	Number of responses	Share of responses	Share of EU/EFTA passenger flow
Yes	0	0	0
No	15	83.3%	67.4%
No reply	3	16.7%	3.9%
Total	**18**	**100.0%**	**71.3%**

EU action is thus necessary to address the fragmentation of the current certification system. The need for EU action to overcome the fragmentation of the certification procedures for aviation security screening equipment was also confirmed by the participants in the public consultation and confirmed by the participants in the workshop.

EU action would also clearly add value as it would allow manufacturers to benefit from an internal market and realise significant savings regarding testing and redesign costs.

None of the options analysed in this Impact Assessment go beyond what is necessary to achieve satisfactorily the objectives set in the following section. As indicated above, it is unlikely that the Member States will take measures to overcome the current fragmentation. The scope of the action would not impede on national security matters or on the existing standards on aviation security.

In fact the aim of this action is to incorporate the non-binding ECAC CEP cooperation agreement of the Member States into EU single-market legislation. The options would not seek to abolish this cooperation agreement of the Member States but merely incorporate it into a more transparent and legally binding EU-wide system.

Further details on the choice of legal instruments are outlined under section "7. Comparing the options - *choice of legislative instrument*".

EU action is therefore justified on grounds of subsidiarity and proportionality.

3. OBJECTIVES

3.1. General policy objectives

The main policy objectives of this initiative are to ensure the **proper functioning of the EU internal market** for aviation screening equipment and to **increase the global competitiveness** of the EU companies operating in this field.

3.2. Specific policy objectives

A specific objective is to avoid unnecessary development, production and administrative cost for producers of aviation screening equipment, and thereby reduce time to market for new products.

Another specific objective is to allow manufacturers to market conform products throughout the EU internal market without double testing or unnecessary product modifications. This should in turn speed up the development and availability of highly performing equipment to meet EU screening and detection requirements.

Finally, it should increase the competitiveness and market access of EU manufacturers in global aviation security markets.

Overview of the objectives

<table>
<tr><th>General Policy Objective</th><th>Specific Policy Objective</th></tr>
<tr><td>Ensure the proper functioning of the EU internal market for aviation screening equipment</td><td>Allow manufacturers to market conform products throughout the EU internal market</td></tr>
<tr><td rowspan="2">Increase the competitiveness of EU companies operating in this field</td><td>Reduce regulatory costs and time to market</td></tr>
<tr><td>Enhance the image of EU products on the global market</td></tr>
</table>

3.3. Consistency with other policies and objectives

Taking action in this area is supporting both the implementation of the policy area "A Deeper and Fairer Internal Market with a Strengthened Industrial Base" of the Political Guidelines of the European Commission outlined by President Juncker as well as the European Agenda on Security, which specifically underlined the importance of a competitive EU security industry for the EU's autonomy in meeting security needs. This specific initiative was also announced in the Commission Communication *"Security Industrial Policy Action Plan for an innovative and competitive Security Industry* (COM (2012) 417)" as "action number 2".[18]

4. POLICY OPTIONS

Five policy options, including the baseline, were developed in the context of this Impact Assessment. These options can be roughly divided in three groups: 1. the baseline scenario; 2. a recommendation to apply the mutual recognition principle; and 3. three regulatory options.

Mutual recognition with the US certification system

An issue which will not be addressed by this initiative concerns the mutual recognition with the US certification system.[19] The central reason for this is the fundamental difference between the US certification system of the TSA and a viable EU-wide certification system. Under the TSA system, the testing is not only free of charge, but the TSA is also participating financially and technically in the development of the equipment to be tested. The US and EU

[18] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0417:FIN:EN:PDF

[19] It should be noted that the current negotiations on the Transatlantic Trade and Investment Partnership (TTIP) are not covering the field of aviation screening equipment.

standards on aviation security are however largely equivalent and are not affected by this initiative.

In the case of mutual recognition, there would be little to no incentive for manufacturers to seek the more costly EU certification. This would eventually make an EU certification system redundant. Given the specific market conditions and the sensitiveness of the security sector, the pursuit of harmonisation between the US and EU systems would be unlikely to yield results in an acceptable timescale.

It should also be underlined that, in order to be certified by the TSA, aviation screening equipment has to be produced in the US. Simply adopting the TSA certification system in the EU would therefore force all EU companies to establish production sites in the US, which would lead to a shift of production from the EU to the US.

Simply transposing the US system on the EU would also imply that the Member States would have to give up authority on the requirements for aviation screening equipment. It would not be acceptable for Member States to give up their prerogatives on national security to the US.

Subsequently, none of the options developed below address the possibility of a Mutual recognition with the US certification system.

1. "Baseline scenario", the Commission would not launch any dedicated policy initiative. As described under section "3.8 Evolution of the problem" and "3.9. EU right to act", it is unlikely that the current sub-optimal conditions on the procedures of certification of aviation screening would be addressed by a Member States 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. The aim of this recommendation would be to enable a producer of an aviation screening equipment to certify his product only once in a single Member State and subsequently be able to sell it in all Member States.

Under this option, the Commission would encourage the Member States to agree on a common, legally binding EU methodology for the certification of aviation screening equipment. This methodology could be based on the ECAC CEP system.

Further recommendations of the Commission to the Member States would address the following aspects:

- The Commission would recommend the Member States to grant an accreditation by a national authority to the testing laboratories which fulfil the requirements set by the common EU methodology. This would ensure that the certifications issued by the laboratory are mutually recognised across the EU, enabling the producers to put their products on the whole EU markets. This accreditation should be open to any laboratory which fulfils the necessary requirements.
- The Commission would also recommend that, contrary to the current system, the producers should be able to select the accredited laboratory at which they want their technology to be tested.
- Additionally, the Commission would recommend to the Member States the creation of a recognisable EU label or brand for those technologies which were successfully certified. This label should enhance the competitiveness of the European producers on the global market.

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. Such a proposal could take different forms. Three different variations will be explained and analysed below. Regulations EC 300/2008[20] on common rules in the field of civil aviation security and EC 185/2010[21] laying down detailed measures for the implementation of the common basic standards on aviation security would apply to all three options.

3.1. The "old approach", or "full harmonisation" is characterised by detailed specifications (technical requirements, testing methodologies and certification criteria) laid down in legislation. Member States' approval authorities certify ex-ante ("type-approval") that the type of product concerned is in conformity with applicable legislation. Conformity assessments are performed by Member States, who may delegate some assessment tasks to appointed "technical services". Only products that comply with the relevant regulatory requirements may be sold or enter into service in the EU.

Since there are already detailed technical requirements and testing methods for aviation screening equipment, it would not be necessary to draft more technical legislation. In this particular case the creation of a harmonised certification system according to the old approach would require the adoption of a legal act establishing the framework for such a scheme. This act would make compliance with the existing requirements mandatory for the sale or entry into service of any aviation screening equipment in the EU, and would stipulate that compliance with these requirements has to be demonstrated by means of the Common Testing Methodologies elaborated within ECAC.

It would, furthermore, set out the administrative procedures to be followed, lay down the obligations of the different actors involved and stipulate how the technical services carrying out the required tests have to be designated and notified. Testing laboratories would be accredited by national authorities, which would issue accreditation on the basis of EU standards. EC-type approval would be granted to equipment which conforms to the technical prescriptions. Equipment which has been granted EC-type approval would be accompanied by a certificate of conformity. Member States would have to permit the sale or entry into force of such equipment, unless there are serious grounds for concern (e.g. threat to safety, more stringent measures, public health or the environment). Conformity certificates would be subject to mutual recognition.

Under this approach ECAC would maintain a key role in implementing the conformity assessment process on the basis of the CTMs developed within ECAC to test compliance with the EU standards on aviation security set out under Regulation (EC) No 300/2008. ECAC would also publish the results of the certifications in the laboratories and continue to act as the interface with the laboratories.

Under this option, the Member States who are actively participating in ECAC's development of the Common Testing Methodologies would keep their central role. Non-EU members of ECAC would still benefit from the equipment tested and certified under the EU/ECAC umbrella.

[20] See (Official Journal L 97 of 9.4.2008):
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:097:0072:0084:EN:PDF
[21] See (Official Journal L 55 of 5.3.2010):
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:055:0001:0055:EN:PDF

3.2. The "new approach", is, unlike the old approach, not based on detailed specifications. Harmonisation is limited to essential requirements, written in general terms. Product legislation is restricted to the requirements necessary to protect the public goals of health and safety. Essential requirements are legally binding in the sense that only products fulfilling these requirements may be sold or placed on the market. Different types of technical solutions can be used to ensure compliance with the essential requirements. However, the application of so-called "harmonised standards", the technical specifications adopted by the European Standardisation Organisations upon request of the European Commission, has the advantage of providing a presumption of conformity with the essential requirements of the applicable legislation. Alternative technical specifications may have the same result, but their conformity with the relevant requirements has to be demonstrated

The establishment of a harmonised certification system for aviation screening equipment according to the new approach would require the drafting of essential requirements for testing labs and accompanying harmonised standards. The essential requirements, set out in a legal act, should be general enough to leave the technical specification to the European Standardisation Organisations which will draw up the standards, but exact enough to cover all hazards that need to be addressed in this sensitive area. The newly adopted legal instrument would also lay down the rules and procedures for conformity assessment. Given the particular nature of the products involved, third-party certification would be more suitable than self-certification. Compliance with the essential requirements would thus be assessed and evaluated by an external conformity assessment body. Products which would meet all requirements laid down in the applicable legislation would receive a CE-mark. With this mark products may be sold in all Member States.

A hurdle in the feasibility of option 3.2 "new approach" concerns the central role of the European Standardisation Organisations and the general way in which standards work. As explained above the existing standards, on which the current legislation for aviation security[22] is based and on which the requirements for the certification process would be based, would have to be made public. This is not the case currently, where access to the standards is restricted depending on security clearance and "need to know basis".

It is unthinkable that this classification will ever be removed, as their content could otherwise be used malevolently to bypass the security controls at airports. This intrinsic feature of the new approach would thus be incompatible with a successful implementation of a legislative proposal.

The option has therefore been discarded.

3.3. The third option, **"the centralised approach"**, is different from the other two options as certification would be carried out centrally by an EU agency. In the particular case of aviation screening equipment certification could be done by the European Aviation Safety Agency (EASA) which is already responsible for the certification of aircraft in the EU and some European non-EU countries. The agency, which was established in 2002 for the purpose of implementing Regulation EC (No) 1592/2002 on common rules in the field of civil aviation establishing a European Aviation Safety Agency, has been in charge of the certification of aircraft, including installed products, parts and appliances since 2003. If EASA would become responsible for the certification of aviation screening equipment as well, the agency would set the rules that would apply for the certification of the equipment and establish a certification

[22] The two relevant regulations are: (EC) No 300/2008 and (EC) 185/2010, Commission Decision 774/2010.

programme in order to test compliance with the criteria. The agency would test the equipment and verify if the products concerned meet the regulatory requirements. Aviation screening equipment which fulfils the criteria would receive a certificate of compliance, issued by EASA. Option 3.3 would thus create an EU-wide procedure for the certification of aviation screening equipment, with a single application, a single evaluation and a single authorisation which would be valid throughout the whole EU.

Under this option, ECAC would not maintain its current role.

5. ANALYSIS OF IMPACTS

The options have been assessed against their potential economic, social and environmental impacts, with a particular focus of their cost-benefits and impacts on the competitiveness of the EU companies.

5.1. Economic impacts

Costs and benefits of the policy options

Option 1 "baseline"

Impacts on competitiveness of EU businesses

Benefits

It is expected that the "baseline" option 1 would have no positive economic impact compared to today. As laid out under section "3.9. EU right to act", it is not likely that the Member States would launch an initiative to overcome the current problems related to the certification of aviation screening equipment. As shown under section "3.8 Evolution of the problem" and considering the current trends, the existing problems are likely to increase to the detriment of the European producers if no action is launched to overcome the current lack of efficiency in the certification process.

It is likely that the lack of action would ultimately lead to an aggravation of the current internal market failure for aviation screening equipment. The world-wide competitiveness of European Manufacturers would likely be hampered in the long run. Their capacity to bring innovative technologies swiftly to the market would also be hindered which would lead to a reduced choice for customers (e.g. airport operators).

The current situation of lack of efficiency for the certification of aviation screening equipment has a negative effect on market efficiency and the competitive situation of EU aviation security screening equipment sector. The lack of harmonisation typical of fragmented markets translates into higher costs and reduces opportunities for achieving economies of scale for equipment suppliers orientated towards European markets.

In addition to the implications that this situation has for price competitiveness, there is concern that the fragmented nature of the European market might have the effect of reducing the overall level of R&D, technology development and innovation. Specifically, market fragmentation implies higher barriers of entry for the adoption of new technologies within the market, potentially reducing the return on investment in development.

Consequently, there may be a negative effect on the competitive position of European suppliers as a result of insufficient investment in technological developments and innovation.

Results of the public consultation for option 1

The results of the public consultation showed that the baseline scenario was judged to have either a very negative or a negative impact on all the areas addressed by the questionnaire.[23]

Option 2 "recommendation"

Costs of the policy option 2

Considering the inherent voluntary nature of a recommendation, there is a degree of uncertainty regarding its costs and benefits. The benefits of option 2 would depend on the willingness of the Member States to implement the recommendations listed above.

In a "best case scenario", where the Member States follow all the recommendations, the benefits could have a positive impact on the free movement of goods, as manufacturers would no longer need multiple certifications to commercialise their product across the EU. In terms of time to market, producers would be able to reduce the time needed to place their products on the market by up to 6 months. In this case, the impacts would be largely identical to those outlined in option 3.1 "old approach".

However, in a "worst case scenario", the Member States would not follow any of the recommendations of the Commission. In this case, the impact of this option would be largely identical to the baseline option, which would lead to a further deterioration of the current competitiveness of the EU aviation screening equipment producers.

Possible impact on appropriate authorities

This option should

- Ensuring that the pre-existing investment of the Member States in ECAC and the development of the CTM are maintained.

Possible impact on Industry/ Equipment manufacturers

Overall this option could lead to a gain of competitiveness for European Producers:

- Reduce the time from development to market of their equipment.
- Reduce the production and commercialisation costs.
- Free up workforce which could be used to develop innovative solutions.
- Create a level playing field with US companies.

Possible impact on airport and air transport hub operators

This option could

- Increase the availability of equipment by a reduction of the time to market.
- Improve their choice of equipment.

Results of the public consultation for option 2

Option 2 was judged by the respondents to have a positive impact on only four aspects: increasing the facilitation[24], reducing research and development costs, ensuring passenger safety and improving passenger flow (i.e. passenger throughput at airports).[25]

[23] See annex 3: Summary of the responses to the public consultation

[24] Facilitation Programme: The ICAO Facilitation (FAL) Programme is based on 10 articles of the Chicago Convention which require that the civil aviation community comply with laws governing the inspection of

This option was judged to have a negative impact on most of the other aspects, including key issues such as the reduction of commercialisation costs, fostering the harmonisation with third countries, for example the US, reduction of time to market of equipment and influencing the competition with non-EU suppliers.

Option 3.1 "Old approach"

Impacts on competitiveness of EU businesses

Costs of option 3.1

The reduction of the need to test multiple times a single piece or 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, as not all the costs are directly related to the price of the certification as such (e.g. the shipping of the equipment).[26]

Laboratories have signalled to the Commission (in August 2015) that they are concerned about potential costs of obtaining accreditation to international standards for the competence of testing laboratories. The use of accreditation to provide an authoritative statement of the competence of a body to perform conformity assessment activities is normal practice in EU single market legislation, as established by Regulation 765/2008, particular in areas of health, safety and security. Assuming a laboratory already meets the necessary quality standards, the Commission considers that the costs of the actual accreditation audit would only amount to around five thousand Euros.[27] These costs would therefore be marginal and would not have an impact on the running costs of the laboratories. The benefits of accreditation include enhancing confidence in the conformity assessment regime, facilitating regulatory compliance and facilitating international trade.

Cost reductions resulting from an EU-wide approach would only have a limited impact on the price competitiveness of EU products on international markets in the short term. Nonetheless, there may be dynamic effects if a less fragmented EU market encourages investment in research, technology development and innovation. In particular, to the extent that the proposed actions are associated to a clear EU approach to aviation security (and regulation, thereof) then this should enhance the attractiveness of investments in relevant security technologies. An EU-wide certification scheme (and corresponding EU security performance 'mark' or 'quality label') may strengthen broader international market awareness and acceptance of EU products.

Benefits of the policy option 3.1

The legislative option 3.1 is expected to have positive economic impacts.

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aircraft, cargo and passengers by authorities concerned with customs, immigration, agriculture and public health. Under the Convention, States are obligated to adopt standards and expedite the necessary formalities in order to minimize operational delays. As the means of carrying out this mandate, the FAL Programme is designed to help States achieve maximum efficiency in their border clearance operations and at the same time achieve and maintain high-quality security and effective law enforcement. Standards and Recommended Practices (SARPs) designed to meet these objectives are developed by ICAO and are maintained in Annex 9 to the Convention. See also : http://www.icao.int/Security/FAL/Pages/default.aspx

[25] See annex 2: Summary of the responses to the public consultation

[26] See SER3Co study, chapter 3.2.4

[27] This assessment is based on market prices, and actual costs incurred by JRC during accreditation.

Regarding option 3.1 one may expect that the existing national authorities in the Member States that currently approve or certify aviation screening equipment, could be tasked to carry out the product certification under this option. However, this would need to be done in only one Member State, as the certificate issued would now be valid in all 28 EU Members States. The JRC survey indicates that currently some 18 Member States are issuing certificates or approvals. Apart from one Member State, the other 27 would no longer need to certify.

Moreover, if successful in reducing market fragmentation in the EU, the proposed policy actions should raise overall EU market efficiency in the aviation security screening sector. However, an EU-wide approach to standards, conformity access and certification may also increase the openness of the EU market to non-EU suppliers. In this regard, EU companies may face increased competition from non-EU suppliers

A harmonisation of the certification procedures should have a positive impact on the free movement of goods, as manufacturers would no longer need multiple certifications to commercialise their product across the EU.

The choice of customers (e.g. airport operators) should also be improved, given they could choose to procure any "EU certified" aviation 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 the time to market. Instead of having to apply and go through several times for a test of a single piece of equipment (i.e. paperwork, travelling to test centres, delegating personnel etc.), manufacturers will only have to go through this process a single time, if successful.

This harmonisation should also have a positive impact on the global competitiveness of European manufacturers, in particular regarding their US competitors.

Direct benefits of option 3.1

A key direct benefit is the reduction of duplication of testing for manufacturers.

Differing national requirements imply that manufacturers need to amend their products to comply with national regulations, which negatively affect production costs. Under the current system, each test implies extensive administrative procedures such as for instance the shipping of the equipment to the testing facility, the preparation of the specific documents for the test, the assignment of staff to follow testing etc. Possible request for redesigns or modifications of the equipment (e.g. adapting the algorithms) due to the test also contribute to an increase of the production costs. The delays due to the possible redesign/modification of the tested equipment should also be reduced, which could accelerate the time to market by up to six months.

Furthermore, a common EU-wide certification scheme brings more clarity on the testing procedure and timing of the procedure than in the baseline. This is positive for manufacturers.

Finally, an EU-wide certification and testing procedure coordinated by an EU recognised organisation could reduce the risk for delays in the testing procedure and is likely to decrease the time to market of aviation screening equipment for European producers. Such time to market improvement has two implications:

- Reduced differences in time to market between European manufacturers. This is not likely to affect the market volume, but will lead to market share shifts between

European manufacturers. It should however lead to an improved choice of commercialised equipment for customers;

- Improved competitive position of European manufacturer's vis-à-vis non-European manufacturers in the European market. This is addressed below under the indirect benefits.

Indirect benefits of option 3.1

An EU certificate could function as a quality mark, which could improve sales of EU manufacturers outside Europe positively. During the interviews manufacturers stated that having an EU Certificate or Formal Approval would benefit their market access in third Countries and following this the EU influence in equipment used in third countries grows. Their experience is that manufacturers that have a product that is "TSA Certified" are using this "TSA stamp" in their sales on third markets, especially emerging markets, as a selling argument. This picture is confirmed in some of the country studies such as South Korea.

A formal EU Certificate for aviation screening equipment could thus also be used EU manufacturers as a sales argument to generate sales in third countries.

A single EU-wide certification system is likely to improve the competitive position of EU manufacturers on the EU market, vis-à-vis their non-EU competitors. Non-EU producers can now easily put their products in several EU countries on the market once they are TSA approved. A common EU certification system implies that these manufacturers have to go through the same route of testing and certification as the EU manufacturers.

A further effect would be that US manufacturers would have to submit their products to the common EU certification system to commercialise them in the EU. This would create equality of treatment between EU and US manufacturers, as EU manufacturers all have to pass the US TSA system to put their technologies on the US market.

The direct benefits for manufacturers would have a negative impact on the sales price of the equipment. It is expected that these costs savings would be passed on, however, based on the current market structure with only a few suppliers per equipment type, the impact on sales price would be relatively low. Similarly, the prices of airline tickets should not be affected.

Impact on appropriate authorities of option 3.1

This option should

- Ensuring that the pre-existing investment of the Member States in ECAC and the development of the CTM are maintained.
- Reduce possible uncertainties related to the certification process.

Impact on Industry/ Equipment manufacturers of option 3.1

Overall this option should lead to a gain of competitiveness for European Producers as they would:

- Improve the transparency of the process and reduce uncertainties related to the certification process.
- Reduce the time from development to market of their equipment.
- Reduce the production and commercialisation costs.
- Free up workforce which could be used to develop innovative solutions.

- Increase their visibility and credibility in the international competition.
- Create a level playing field with US companies.

Impact on airport and air transport hub operators of option 3.1

This option should

- Improve the transparency of the process.
- Increase the availability of equipment by a reduction of the time to market.
- Improve their choice of equipment.

Results of the public consultation for option 3.1

A broad positive support was expressed by the respondents on option 3.1, the regulation based approach. The respondents judged it to have a potentially very positive impact on seven aspects: research and development costs, commercialisation costs, harmonisation with third countries, the competition with non-EU suppliers, better guidance to procurers, Improve mutual trust in Member States' aviation security and Simplify the procurement process of aviation screening equipment for airport operators or their procurement agencies.

The only aspect where this option was judged to have a potential negative impact concerned the optimisation of airport space.

Option 3.3 "centralised approach"

Impacts on competitiveness of EU businesses

If successful in reducing market fragmentation in the EU, the proposed policy actions should raise overall EU market efficiency in the aviation security screening sector. However, an EU-wide approach to standards, conformity access and certification may also increase the openness of the EU market to non-EU suppliers. In this regard, EU companies may face increased competition from non-EU suppliers.

Costs of option 3.3

In addition to the costs laid out under option 3.1, the main costs of option 3.3 would be the increase of EASA (staff) required to accommodate the additional certification task.

The current staff of ECAC can be taken as a basis for the increase of staff required at EASA to cover these tasks. ECAC has a total of 14 employees working at the secretariat. All the other collaborators (auditors, chairs of the different working groups) are not paid by ECAC, but by the Member States. The current budget of ECAC for three years is € 6,000,000, i.e. average of € 2,000,000 per year. Around 80% of this budget is used to pay the secretariat. No staff would be saved at the level of national authorities.

It should be noted in this context that the current revision of the EASA regulation 216/2008 does not foresee the possibility of extending the competences of EASA to cover certification or conformity assessment of aviation security equipment. In fact the Impact Assessment on the revision explicitly mentions the need to address the current fragmentation:

"In addition, the EASA Opinion highlighted the need for an EU mechanism for conformity assessment of aviation security equipment, the absence of which is currently considered a stumbling block towards the creation of an EU market for manufacturers of airport screening

and explosive detection equipment. With respect to this issue, a separate initiative is ongoing under coordination of DG HOME."

Extending the staff of EASA to cover certification aspects would also be complicated by the reduction of staff by 5% which has to be applied to all EU agencies.

Finally, during the workshop, all participants, including Member States representatives agreed that ECAC should continue to play a central role in a possible future harmonised certification system for aviation screening equipment. A possible involvement of EASA was not mentioned by any of the participants. The willingness of the Member States or political feasibility to considerably extend the staff of EASA to cover these tasks is doubtful.

Benefits of option 3.3

The benefits for Option 3.3 should be similar to those of options 3.1, regarding the free movement of goods, the choice of buyers, and the competitiveness of EU producers. The additional costs generated by an extension of staff at EASA should be offset by savings for other certifying bodies.

Impact on appropriate authorities of option 3.3

This option should

- Ensuring that the pre-existing investment of the Member States in ECAC and the development of the CTM are maintained.
- Reduce possible uncertainties related to the certification process.

Impact on Industry/ Equipment manufacturers of option 3.3

Overall this option should lead to a gain of competitiveness for European Producers as they would:

- Improve the transparency of the process and reduce uncertainties related to the certification process.
- Reduce the time from development to market of their equipment.
- Reduce the production and commercialisation costs.
- Free up workforce which could be used to develop innovative solutions.
- Increase their visibility and credibility in the international competition.
- Create a level playing field with US companies.

Impact on airport and air transport hub operators of option 3.3

This option should

- Improve the transparency of the process.
- Increase the availability of equipment by a reduction of the time to market.
- Improve their choice of equipment.

Results of the public consultation for option 3.3

The centralised approach (3.3) was judged to have the highest potential for a positive impact on all questions. The respondents favoured this option independently of their background. It was judged to be very positive on 12 aspects and positive on 3 further aspects.

Main conclusions from the Cost-benefit analysis

Option 1 would not meet the objectives of this initiative.

The benefits of option 2 would depend on the willingness of the Member States due to the voluntary character of the option.

The benefits of options 3.1 and 3.3 are similar. The benefits of option 3.3 would however depend on the willingness of the Member States to extend the staff of EASA.

Overall, the main benefits for industry would lie in a faster certification process which would reduce the time to market and improve the availability of novel technologies for airport operators.

Direct benefits in terms of reduced duplication of testing would remain limited considering the absolute cost savings for the process from development to commercialisation.

A further substantial benefit of the sub-options 3 is indirect: a European certificate brings European manufacturers 'on par' with their US competitors on markets in emerging markets and in Europe. The improved competitive position will increase revenue for the manufacturers and value added for the European economy. This is irrespective of the sub option chosen. Surveys held with eight manufacturers did not reveal any preference in this respect, as long as one of the sub-option 3 was implemented.

Comparison of costs and benefits for options (compared to baseline)

+ = positive impact, - = negative impact, 0 = no impact, ? = unclear impact

	Option 1 (baseline)	**Option 2[28]**	**Option 3.1**	**Option 3.3**
Impacts for EU Industry				
Increased clarity on testing procedure	0	+	+	+
Efficiencies in production	0	+	+	+
Reduced risk for delays and improved time to market	0	+	+	+
Impacts for authorities				
Reduced costs for issuing certificates	0	+	+	+
Impacts for testing laboratories (TL)				
Verification costs of TLs work	0	*0*	0	0
Reduced revenues for TL[29]	0	-	-	-
Impacts for European Standardisation Organisations				
Costs for standards development	0	*0*	0	0
Impacts for end users				
Reduced product price[30]	0	+	+	+

5.2. Social and environmental impacts

The social impacts and environmental impacts of the options would be relatively limited.

[28] All the estimations under this option would depend on the willingness of the Member States to apply the recommendations.

[29] The reductions would be due to the reduction of tests for equipment across the EU.

[30] The reductions would be relatively marginal, given that the impact of the testing costs on the production are below 1%.

The only notable social impact concerns employment in the aviation screening equipment sector.

The increase in competitiveness expected in the options 2, 3.1 and 3.3 should lead to an overall increase of sales of EU manufacturers in third countries, as described in the table above. This increase of sales should in turn have a positive impact on the overall employment figures in the aviation screening equipment sector. It is not possible however to precisely quantify this impact considering that there are no definite indications on the overall employment figures in the sector.

This positive effect would not be triggered through option 1, as this option would not lead to an increase of competitiveness and hence not increase sales figures.

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.

6. COMPARING THE OPTIONS

Overview of the Economic, social and environmental impacts

	Option 1	Option 2	Option 3.1	Option 3.3
ECONOMIC IMPACTS				
Functioning of the internal market	-	0/++	++	++
Compliance costs for businesses	-	0/+	+	+
Administrative burden for businesses	-	0/+	+	+
Innovation	-	0/++	++	++
SMEs	-	0/++	++	++
International relations	-	0/+	+	+
Competitiveness	-	0/+	+	+
Implementation costs for public authorities	0	0/+	+	+
SOCIAL IMPACTS				
Number and quality of jobs	-	0/+	+	+
ENVIRONMENTAL IMPACTS	0	0	0	0

The "baseline" does not address the problems. Without a policy initiative to support the competitiveness of the European manufacturers it is expected that the market shares of these companies on the global market would decrease constantly over the next years.

The effectiveness of a non-binding option as examined under option 2 would largely depend on the willingness of the Member States. The possible impacts of this option are therefore uncertain.

The two legislative options, 3.1 "old approach", and 3.3 "centralised approach" had similar scores in terms of possible impacts. Both would lead to roughly identical cost savings.

Stakeholders expressed a comparable support for each of the two legislative policy options.

Political feasibility

The determining factor to select the option having the most significant positive impact relies on the political feasibility of introducing an initiative to harmonise certification systems for aviation screening equipment.

If Member States intended to launch such an initiative on their own, they would have already have taken some or all the steps in option 2. We therefore conclude that intervention is needed at EU level. This was confirmed by the public consultation which concluded that option 2 would have a negative impact on key issues such as reduction of commercialisation costs, reduction of time to market of equipment and influencing the competition with non-EU suppliers.

The political feasibility of the centralised approach is considerably hampered by the need to extend the staff and role of EASA. Such an extension, and the subsequent increase of costs it would include, is unlikely in the current political climate of general reduction of officials in public administration/agencies. It would be even more unlikely when considering that Member States already invested in the creation, running and maintenance of the ECAC Common Evaluation Process (CEP).

This last point was further emphasized during the workshop organised as a follow up to the public consultation, which showed that the dominant concern of the stakeholders, including both the Member States and industry, was to ensure the continuity of ECAC. The Member States have invested considerably in the development of the Common Testing Methodologies at ECAC and none of them expressed interest for an extension of the role of EASA. All stakeholders agree that these CTM are the best available system in the EU and that they should continue to play a central role. The increased cooperation in ECAC which could be observed recently and the subsequent decrease of testing duplications for aviation screening equipment is a further indicator for the support of the ECAC CEP system in the EU.

Option 3.3 can thus be considered to have limited political feasibility.

The “old approach” harmonisation based on the ECAC system would therefore be the most feasible option with significant positive impacts, with the broadest support among all stakeholders, including Member States.

Effectiveness, efficiency and coherence

Effectiveness: Options 3.1 and 3.3 are expected to be more effective than option 1 and 2. Both 3.1 and 3.3 address the specific objectives of this initiative.

The effectiveness of option 2 is uncertain as its implementation would depend on the willingness of the Member States. Option 1 would not be effective on these two central objectives.

Efficiency: Option 3.1 is expected to be more efficient than options 1, 2 and 3.3 in meeting the objectives described under "section 4 Objectives", as it would ensure the broadest support of all stakeholders for the establishing a harmonised certification system for aviation screening equipment without generating additional administrative burden or costs at Member State level.
Option 3.3 would be less efficient than option 3.1 as it would have a lower political feasibility and generate additional costs in EASA. The efficiency of option 2 is again uncertain as its implementation would depend on the willingness of the Member States.

Coherence: Options 2, 3.1 and 3.3 would all be coherent with the objectives of the *"Security Industrial Policy"*[31], the Political Guidelines of President Juncker[32] and the European Agenda on Security[33] to increase the competitiveness of EU companies by overcoming the fragmentation of the internal market and contributing to the EU's autonomy in meeting security needs. Option 1 would not be coherent with these objectives as it would have no positive impact on any of the objectives of these policy initiatives.

Comparison of Policy Options in terms of their effectiveness, efficiency and coherence of responding to the operational policy objectives

Operational Policy Objective	Option 1	Option 2	Option 3.1	Option 3.3
Create a clearer common EU-wide certification system	-	0/+	0/++	0/++
Improve the choice available to customers (e.g. airport operators)	-	0/+	0/++	0/++
Eliminate the need for multiple testing	-	0/+	0/++	0/++
Eliminate the need for MS-specific modifications	-	0/+	0/++	0/++
Create a more investment friendly environment for security technologies.	-	0/+	0/++	0/++
Create a label showing compliance with EU regulatory requirements	-	0/+	0/++	0/++
Create a level playing field with US companies.	-	0/+	0/++	0/++

Choice of legislative instrument

One issue which arises from this conclusion is the identification of the most appropriate legislative instrument to use for the initiative, i.e. either a regulation or a directive.

The relevant legal basis, Art. 114 TFEU, does not specify a particular instrument.

Regulations are directly applicable and do not need additional transposition measures. Directives on the other hand are not directly applicable and allow Member States to choose appropriate measures to achieve the aims stated in the directive, as long as they meet them before the transposition deadline stated in the instrument's text.

When there are large discrepancies between Member States in terms of administrative, political and social arrangements, when country's legal systems deal differently with an issue or when it is difficult to come to an agreement which is precise and specific enough to regulate a subject matter without requiring any (further) transposition measures, a directive is better adapted at regulating a matter than a regulation.

Taking into account the aims of this particular proposal, the specific context and the content, a regulation seems better suited than a directive considering the need for a clear framework in the form of a harmonised certification system, based on the already existing regulations EC 300/2008 and EC 185/2010.

[31] COM (2012) 417
[32] "A Deeper and Fairer Internal Market with a Strengthened Industrial Base"
[33] COM(2015) 185 final

7. MONITORING AND EVALUATION

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[34]. This survey will be launched through a contract with an external contractor, which will also collect the data for the 2010-15 annual mean.

This survey will address the following indicators with a view to assess whether the implementation of the regulation led to a:

- Reduction of research and development costs; i.e. by how much EUR per piece of aviation screening equipment per year have the costs associated with adaptation of the equipment be reduced in comparison to annual mean 2010-2015?
- Reduction of commercialisation costs; i.e. by how much have the costs of complying with different national requirements be reduced per piece of aviation screening equipment per year in comparison to annual mean 2010-2015?
- Recognition of EU certification; i.e. in how many cases has EU certification been used in third countries of the tenders for procurement of aviation screening equipment per year in comparison to annual mean 2010-2015?
- Reduction of time to market of equipment; i.e. by how many months has the average time to market for a piece of aviation screening equipment been reduced in comparison to 2015?.
- Improving the competition with non-EU suppliers; has there been a case where a non-EU supplier could place his equipment on the EU market without an EU certification?

[34] i.e. Create a clearer common EU-wide certification system; Improve the choice available to customers (e.g. airport operators); Eliminate the need for multiple testing; Eliminate the need for MS-specific modifications; Promote competition between accredited test centres; Create a more investment friendly environment for security technologies; Eliminate the need for multiple applications for certification; Increase testing capacity by facilitating the accreditation of new test centres; Create a label showing compliance with EU regulatory requirements; Create a level playing field with US companies.

ANNEX 1: LIST OF ACRONYMS

ACI	Airports Council International
CENELEC	Comité Européen de Normalisation Électrotechnique/European Committee for Electrotechnical Standardization
CEN	Comité Européen de Normalisation/European Committee for Standardisation
CEP	Common Evaluation Process of security equipment
CTM's	Common Testing Methodologies
TTF	ECAC Technical Task Force
EASA	European Aviation Safety Agency
ECAC	European Civil Aviation Conference
EDS	Explosives Detection Systems
EFTA	European Free Trade Association
ETSI	European Telecommunications Standards Institute
IATA	International Air Transport Association
ICAO	International Civil Aviation Organisation
LEDS	Liquid Explosive Detection Systems
SSc	Security Scanners
SER3CO	Study on security R&D in major 3rd countries
TFEU	Treaty on the Functioning of the European Union
TSA	US Transportation Security Administration

ANNEX 2: GLOSSARY

Accreditation

What is accreditation?

Accreditation is the last level of public control in the European conformity assessment system. Accreditation is designed to ensure and attest that conformity assessment bodies (e.g. laboratories, inspection or certification bodies) have the technical capacity to perform their duties adequately.

Accreditation is used in both the regulated sector to meet the requirements of certain legislation and the voluntary area where there is no specific legislation.

Accreditation aims to increase trust in conformity attestation and thus reinforces the mutual recognition of products, processes, services, systems, persons and bodies across the EU.

It is based on a peer evaluation system that ensures the proper functioning of accreditation across the EU.

How does accreditation work?

Accreditation of conformity assessment bodies is based on international standards, which define competence criteria for the national accreditation body and for each category of conformity assessment body (such as laboratories or certification bodies), sector specific requirements and guidance documents drawn up by regional and international organisations of accreditation bodies.

Accreditation in the EU

Regulation 765/2008, which sets out requirements for accreditation and market surveillance relating to the marketing of products, establishes the legal framework for accreditation in Europe.

The Regulation promotes a uniformly rigorous approach to accreditation across Member States – so that ultimately one accreditation certificate will be enough to demonstrate the technical capacity of a conformity assessment body.

The main principles of accreditation in the Regulation (which complement the relevant international standard for accreditation bodies) are:

One accreditation body per Member State (but it is possible to have recourse to another Member State's national accreditation body, should a Member State decide not to set up its own).

- Accreditation is a public sector activity.
- There is no competition between national accreditation bodies.
- Accreditation is a not-for-profit activity.
- Stakeholder representation is ensured.
- Accreditation is the preferred means of demonstrating technical capacity in the regulated area - in the appointment of notified bodies.

Furthermore, Regulation 765/2008 recognises a body known as the European co-operation for accreditation, the EA, of which national accreditation bodies are members and which cooperates with the European Commission.

It is EA's task to set up and manage a sound peer evaluation system of national accreditation bodies – to ensure that each accreditation body functions properly and has the competence needed to perform its tasks.

EA also provides technical assistance to the Commission in the field of accreditation.

For this purpose, in 2009, the Commission, European Free Trade Association (EFTA), Member States and EA signed general cooperation guidelines that mark their political commitment to work closely together and prepare for the successful implementation of the accreditation chapter of the Regulation.

In June 2010, the Commission and EA signed a framework partnership agreement for the period 2010-2014. This framework partnership agreement allows financial support for EA in fulfilling its tasks under the Regulation and meeting the objectives set out in the guidelines.

Conformity Assessment

1. Conformity assessment of products

The free movement of goods is a cornerstone of the single market. The mechanisms in place to achieve this aim are based on the prevention of new barriers to trade, on mutual recognition and on technical harmonisation. Placing a product on the market and putting it into service can only occur once it is deemed to comply with the provisions of all applicable technical harmonisation legislation and once a conformity assessment has been carried out in accordance with that legislation. The manufacturer has an obligation to ensure that a product intended to be placed on the EU market is designed and manufactured in conformity with essential requirements laid down in applicable legislation and to confirm that this conformity has been assessed. Conformity assessments include activities such as testing, inspection and certification to determine that a product fulfils the relevant requirements of applicable technical harmonisation legislation.

Conformity assessments must not be confused with market surveillance, which consists of controls after the product has been placed on the market. However both techniques are complementary and equally necessary to ensure the smooth functioning of the internal market.

The assessment of the conformity of a product is carried out before that product is placed on the market and consists of demonstrating that it fulfils all the legislative requirements that apply to it. Conformity assessments are performed in accordance with technical procedures specified in sectorial legislation.

Manufacturers may choose between different conformity assessment procedures provided for in the applicable directive(s). The assessment of the conformity of a product may be carried out either by the manufacturer himself or by a conformity assessment body (‘in-house’ or 'external' ; see notified bodies), depending on the provisions of the modules selected by the relevant sectorial legislative instrument.

1.1 Conformity assessment procedures and Declaration of Conformity

The essential objective of a conformity assessment procedure is to demonstrate to public authorities that a product being placed on the market conforms to the requirements expressed in relevant legislation, in particular with regard to the health and safety of users and consumers. The purpose of conformity assessment procedures is thus to ensure confidence on all sides in a product’s conformity to the relevant essential requirements. As a general rule, a product should comply with conformity assessment requirements throughout the design and production phases.

1.1.1 The modules

Conformity assessment is subdivided into modules, and conformity assessment procedures are composed of one or more conformity assessment modules. The modules relate either to the design phase of products, the production phase, or both. A conformity assessment procedure should cover both the design and production phases, while a module may cover either one of these phases (when a conformity assessment procedure is composed of two modules) or both (when a conformity assessment procedure comprises just one module).

Each directive describes the range and contents of possible conformity assessment procedures, which are considered to give the necessary level of protection. The directives also set out the criteria governing the conditions under which the manufacturer can make a choice, if more than one option is provided for.

1.1.2 EC Declaration of Conformity

Manufacturers, or their authorised representatives, with a legal base in the EU must draw up an EC Declaration of Conformity (DoC) as part of the conformity assessment procedure provided for in the applicable legislation. The EC Declaration of Conformity should contain all relevant information to identify the legislation according to which it is issued, as well as the manufacturer, the authorised representative, the notified body if applicable, the product, and where appropriate a reference to harmonised standards or other normative documents.

Notified Bodies

1.1 Notification procedure and withdrawal of notification

Notification is an act to inform the Commission and the other Member States that a body, which fulfils the requirements, has been designated to carry out conformity assessment according to technical harmonisation legislation. The Commission publishes lists of notified bodies for information purposes on its website for Notified Bodies, NANDO.

Withdrawal of notification takes place when the notified body ceases to fulfil the afore-mentioned requirements or its obligations. Withdrawal is the responsibility of the notifying Member State. It can also be the end result of an infringement procedure.

1.2 Principles of notification

Notified bodies carry out the tasks pertaining to the conformity assessment procedures referred to in the applicable technical harmonisation legislation when a third party is required. It is the responsibility of Member States to notify those ('external') conformity assessment bodies within their jurisdiction that are technically competent to assess the compliance of products with the requirements of applicable directives(s). They may choose from among all the bodies under their jurisdiction which comply with the requirements of the directives and the principles laid down in Decision EC/2008/768.

The assessment of the body seeking notification determines if it is technically competent and capable, and if it can demonstrate the level of independence, impartiality and integrity necessary to carry out the conformity assessment procedures in question. Further, the competence of the notified body should be subject to surveillance, which should be carried out at regular intervals and should follow the practice established by the accreditation organisations.

The EN ISO/IEC 17000 series of standards and accreditation are important supporting instruments in establishing conformity with the requirements of the applicable legislation.

In-house bodies do not need to be notified but they must still demonstrate the same technical competence as external bodies. Member States must ensure that in-house bodies also maintain their technical competence.

1.3 Notified bodies and conformity assessment

As previously mentioned, the primary task of a notified body is to provide services for conformity assessment under the conditions set out in the directives. This is a service to the manufacturers in an area of public interest. Notified bodies are free to offer their conformity assessment services, within their scope of notification, to any economic operator established either inside or outside the EU. They may also carry out these activities on the territory of other Member States or of third countries.

Manufacturers are free to choose any notified body that has been designated to carry out the conformity assessment procedure in question according to the applicable directive.

1.4 General responsibilities of notified bodies

Notified bodies must operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner. They must employ the necessary personnel, with sufficient and relevant knowledge and experience to carry out conformity assessment in accordance with the directive(s) in question.

Notified bodies must make adequate arrangements to ensure confidentiality of the information obtained in the course of conformity assessment, and be adequately insured to cover their professional activities, unless liability is assured under the national legislation of the notifying Member State. They must also provide relevant information to their notifying authority, the market surveillance authorities and other notified bodies.

1.5 Notified bodies and subcontracting

A notified body can subcontract part of its work to another body on the basis of established and regularly monitored competence. The subcontracted body must be technically competent and display independence and objectivity according to the same criteria and under the same conditions as the notified body. However, notification is not necessary. The Member State that has notified the subcontracting body must also be capable of ensuring effective monitoring of the competence of the subcontracted body.

A further condition for subcontracting is that the conformity assessment procedure can be subdivided into technical operations and assessment operations, and that the methodology used to carry out the technical operations is sufficiently precise. The body subcontracted by the notified body must, nevertheless, carry out substantial and coherent parts of these technical operations.

Subcontracting must be based on a contract which makes it possible to ensure the transparency of and have confidence in the notified body's operations. A subcontracting notified body remains responsible for all the activities covered by the notification. Subcontracting does not entail the delegation of powers or responsibilities. Certificates are always issued in the name and under the responsibility of the notified body. The conditions for subcontracting apply to any subcontractor whether established within the Community or not.

1.6 Coordination and cooperation of notified bodies

Notified bodies participate in coordination activities. Coherent application of the conformity assessment procedures requires close cooperation between the notified bodies, the Member States and the European Commission. The Commission supports the Member States in their efforts to establish coherence among the notifying authorities regarding, in particular, the assessment of the competence of the bodies to be notified, the application of notification procedures and the surveillance of notified bodies. The Commission, in coordination with Member States, also ensures that cooperation is organised between the notified bodies. They should also take part, whether directly or by representation in European standardisation, or are up-to-date with current relevant standards.

1.7 The NANDO website

The Member States, EFTA countries (EEA members) and other countries with which the EU has concluded Mutual Recognition Agreements (MRAs) and Protocols to the Europe

Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs) have designated Notified Bodies, established per directive. Lists of Notified Bodies can be searched on the NANDO website (New Approach Notified and Designated Organisations). The lists include the identification number of each notified body as well as the tasks for which it has been notified, and are subject to regular update.

The lists of notified bodies are given for information only and are valid at the date indicated. Information is made available as provided by the designating authorities of the Member States. Any comments concerning the information contained in the lists should be addressed directly to the relevant authorities in the Member States responsible for the designation of the bodies.

ANNEX 3: PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

Identification

Lead DG: DG HOME

Other involved DGs: DG MOVE, DG JRC, DG GROW

Agenda Planning/WP Reference:

Organisation and timing

The work for this Impact Assessment started in November 2012.

An impact assessment steering group was set up to which DG HOME, DG GROW, DG JRC, SG, LS, DG MARKT and DG JUST participated. A total of four meetings of the Impact Assessment Steering Group were held on 28 November 2012, 8 February 2013, 11 May 2015 and 30 September 2015.

Scrutiny by the Commission Impact Assessment Board

The Impact Assessment Board of the European Commission assessed a draft version of the present impact assessment and issued its opinion on 03/07/2015. The Regulatory Scrutiny Board made several recommendations and, in the light of the latter, the final impact assessment report:

- Gives more information on the public consultation and the background on the stakeholders.
- A passage on TTIP has been added.
- The relation between the EU and US has been expanded. The differences between the ECAC and the TSA have been expanded.
- The problem definition has been revised and streamlined. Clarifying the drivers, problems and consequences. Adding the objectives to the problem tree.
- The operational policy objectives have been expanded and the objectives in general have been streamlined.
- The role non EU Members of ECAC would play in the proposed legislation has been detailed.
- Sections on the different stakeholder groups and how they are affected were added.
- The information on ECAC and the CEP has been updated.
- The Impacts section was revised.
- The section on monitoring has been clarified.
- The relation to the EASA revision has been made clearer.
- Paragraph was added on the possible costs related to ISO standards acquisition.

ANNEX 4: STAKEHOLDER CONSULTATIONS

This IA builds both on internal and external expertise. Relevant data has been collected through:

- An open Public Consultation on the Certification of Aviation Screening Equipment which ran from 5 March 2013 to 10 June 2013. The consultation was published on Your Voice in Europe. The results of the public consultation have been added below.

  The consultation received 37 contributions. Despite this relatively low response rate, the results of the public consultation can be considered as representative. All stakeholder groups (national administrations, all types of enterprises (including SMEs), test laboratories, airport operators etc.) were represented.

  Additionally, the main associations of the sector, such as the main airlines association, representing some 240 airlines or 84% of total air traffic and the main business association, representing most EU manufacturers and several testing labs contributed to the consultation, effectively representing several hundred of stakeholders.

Stakeholder background	Number of replies
Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	4
Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
Large enterprise (more than 250 employees)	8
A business association	4
A national administration	8
An academic institution or think tank	1
A non-governmental organisation	1
A security services provider	3
An airport operator	5
A test laboratory	2

The respondents came from sixteen countries, including twelve Member States and four non-EU countries (Norway, Switzerland, Bosnia and Herzegovina, and Turkey). The participants reflected well the views of the relevant community and can be considered as representative for the stakeholders in the aviation security sector. The results of the public consultation have also been uploaded to the website of the consultation.[35]

The aim of this consultation was to ensure that the initiatives planned by the Commission address issues which are a true concern for the EU and that no stakeholder group is affected in a disproportionate manner.

The public consultation was divided in four sections:

[35] See: http://ec.europa.eu/enterprise/policies/security/industrial-policy/consultation-on-airport-screening-equipment/index_en.htm

1) Problem definition: an essential aspect was to inquire among all relevant stakeholders on the preliminary problem assessment made by the Commission, i.e. defining the general need and the specific areas on which action is required. Respondents were asked to reply to a set of questions based on the same baseline: "What effect do you think the current situation where there is no harmonised certification system for aviation security equipment has had on […]". This question was asked for 17 different issues, three of which reserved solely for industry. The full list of questions can be found below.

2) Assessing the impact of the options: the aim of this section was to assess which of the five policy options presented by the Commission was judged to have the most positive impact on a set of 15 aspects, such as development costs or the time to market of equipment. The full list of questions can be found under below.

3) Technical questions on the certification process: this section focussed on specific technical details on a possible harmonised certification process for aviation screening equipment.

4) The role of the European Civil Aviation Conference (ECAC): the last section inquired on the role ECAC could or should play in the context of a possible harmonised certification process for aviation screening equipment.

It should be underlined that the different stakeholder groups gave largely homogeneous replies to these questions. No major discrepancies among the various groups were identified.

- A workshop was organised as a follow up to the public consultation on 25 September 2013. The workshop was well attended and comprised representatives from all the concerned stakeholder groups, including the industry, the European Civil Aviation Conference (ECAC) representing the central member States organisation on aviation screening equipment and end-users representatives (Airports Council International Europe).

  The central aim of this workshop was to present the conclusion of the Commission analysis on the public consultation, as well as the outcomes of the external *"Study on Civil Security R&D in major third countries"*[36] and of the Commission's Joint Research Centre (JRC) study on *"Detection Requirements and Testing Methodologies for Aviation Security Screening Devices in the EU and EFTA*.

  Moreover, each stakeholder group had the opportunity to present and discuss their views on the current state of play of the certification of aviation screening equipment.

  The main conclusion of the workshop was the convergence of the results of the studies presented during the first session, in terms of both problematic issues and potential solutions. A summary report of this Workshop can be found in annex 2.

[36] This study comprised an extensive analysis of the certification and conformity assessment procedures for aviation screening equipment.

Even though a certain time elapsed between the public consultation, the workshop and the submission of the Impact Assessment, these findings from these consultations remain valid on the central issue addressed in this Impact Assessment: the lack of common legally binding procedures for the certification of aviation security screening equipment in the EU Member States. This has been confirmed during bilateral discussions with all relevant stakeholders over the last months.

A further survey on "Detection Requirements and Testing Methodologies for Aviation Security Screening Devices in the EU and EFTA" carried out by the JRC and published in spring 2013. The aviation security authorities of 27 EU and EFTA Member States responded to the questionnaire. The full report can be found under the following link: https://erncip-project.jrc.ec.europa.eu/networks/tgs/avsec.

- A study carried out by an external contractor in support of this Impact Assessment entitled "Study on security R&D in major 3rd countries" (referred to as "SER3CO" in this Impact Assessment). 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. The final report of the study can be found under the following link; http://ec.europa.eu/enterprise/policies/security/documents/index_en.htm.
- A study carried out by an external contractor in support of an earlier Impact Assessment in 2012 for the 2012 Security Industrial Policy Communication "Action Plan for an innovative and competitive Security Industry" entitled: "Regulatory Framework and Certification/Conformity Assessment Procedures in the Security Sector (referred to as SECERCA study in the footnotes)".[37]

The Commission's minimum standards for consultation and expertise in the context of Impact Assessments have been met.

The results of these consultations have been fully taken into account in the present IA report when defining the problems and analysing the options.

Summary of responses to the public consultation

The European Commission conducted a public consultation on the Certification of Aviation Screening Equipment. An electronic questionnaire was published on the Your Voice in Europe website and interested parties were invited to submit their contributions from 15 March 2013 to 10 June 2013. The consultation was open to all interested parties, with distinctive modules for industry representatives, and other stakeholders.

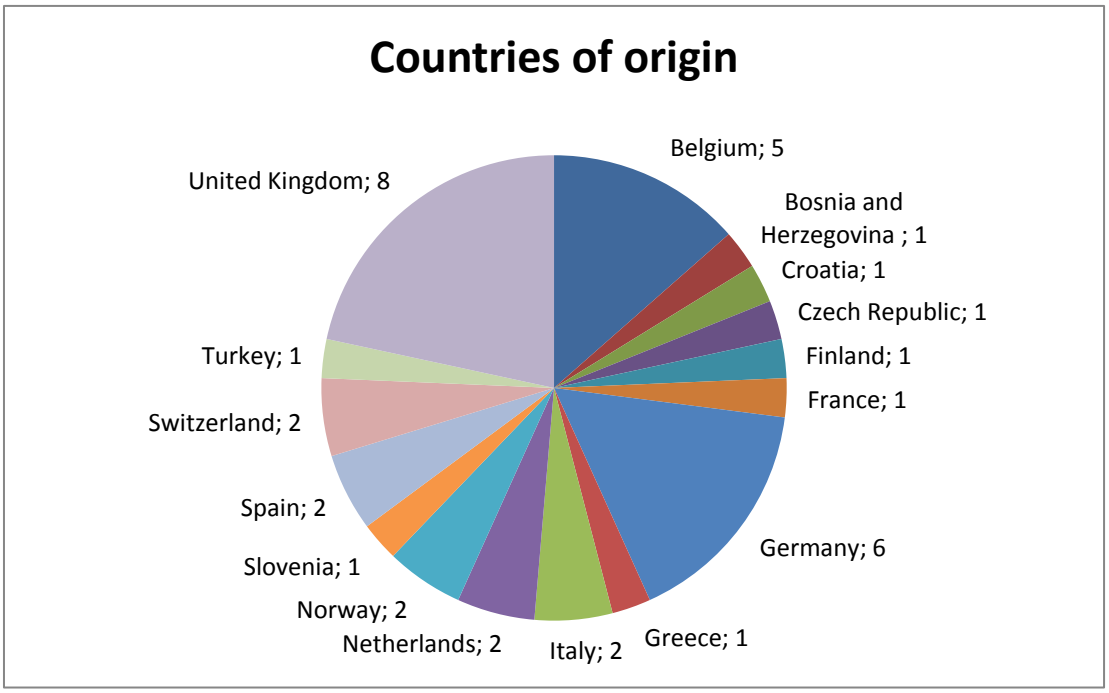
The consultation received 37 contributions. Respondents included:

Stakeholder background	Number of replies
Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	4

[37] See: http://ec.europa.eu/enterprise/policies/security/documents/index_en.htm

Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
Large enterprise (more than 250 employees)	8
A business association	4
A national administration	8
An academic institution or think tank	1
A non-governmental organisation	1
A security services provider	3
An airport operator	5
A test laboratory	2

The responents came from the following countries



1. Problem Definition

1.1 Problems related to the fragmentation of the certification procedures

This initiative is the first Commission led attempt to harmonise the currently fragmented certification procedures for aviation screening equipment in the EU. An essential aspect was thus to inquire among all relevant stakeholders on the preliminary problem assessment made by the Commission. The participants were thus asked the question: **"What effect do you think the current situation where there is no harmonised certification system for aviation security equipment has had on"**.

The responses have been grouped according to the following categories:

A. Very significant problem:

- **Harmonisation with third countries**, for example the US - 81,08% of the respondents answered either with very negative effect or negative effect. All stakeholder groups underlined the negative aspects with the exception of the national administrations, which did not identify this as a problem.

Harmonisation with third countries, for example the US	Type of respondent	Total
No response	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
No response Total		**1**
Do not know	An airport operator	1
Do not know Total		**1**
Very negative effect	A business association	2
	A non governmental organisation	1
	A security services provider	3
	An academic institution or think tank	1
	An airport operator	4
	Large enterprise (more than 250 employees)	4
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Very negative effect Total		**16**
Negative effect	A business association	2
	A national administration	3
	A test laboratory	2
	Large enterprise (more than 250 employees)	4
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Negative effect Total		**14**
Positive effect	A national administration	4
Positive effect Total		**4**
Very positive effect	A national administration	1
Very positive effect Total		**1**
Grand Total		**37**

- **The efficiency of the certification process** - 78,38% of the respondents answered either with very negative effect or negative effect. The majority of the participants (all industry, business association, airport operators, services providers, NGO) identified this as a major problem. National administrations were divided on this matter and test laboratories did not consider this to be an issue.

The efficiency of the certification process	Type of respondent	Total
Very negative effect	A business association	3
	A non governmental organisation	1
	A security services provider	2
	An airport operator	5
	Large enterprise (more than 250 employees)	5
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Very negative effect Total		**18**
Negative effect	A business association	1
	A national administration	2
	A security services provider	1
	An academic institution or think tank	1
	Large enterprise (more than 250 employees)	3
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Negative effect Total		**11**
No effect	A national administration	2
	A test laboratory	1
No effect Total		**3**
Positive effect	A national administration	3
	A test laboratory	1
Positive effect Total		**4**
Very positive effect	A national administration	1
Very positive effect Total		**1**
Grand Total		**37**

- **Legal certainty** - 78,38% of the respondents answered either with very negative effect or negative effect. The majority of the participants (all industry except one, business association, airport operators, test labs, NGO) saw this as a problem. National administrations were divided on this matter four out of six stated that legal certainty was not affected, while two disagreed entirely. The security services provider representative did not identify this as a problem.

Legal certainty	Type of respondent	Total
Very negative effect	A business association	3
	A non governmental organisation	1
	A security services provider	1
	A test laboratory	1
	An academic institution or think tank	1
	An airport operator	4
	Large enterprise (more than 250 employees)	5
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
Very negative effect Total		**17**
Negative effect	A business association	1
	A national administration	2
	A security services provider	1
	A test laboratory	1
	An airport operator	1
	Large enterprise (more than 250 employees)	2
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	4
Negative effect Total		**12**
No effect	A national administration	4
	A security services provider	1
	Large enterprise (more than 250 employees)	1
No effect Total		**6**
Positive effect	A national administration	2
Positive effect Total		**2**
Grand Total		**37**

- **Research and development costs** - 72,97% of the respondents answered either with very negative effect or negative effect. All industry representatives except one identified this as a major problem. The majority of national administrations did not consider this to be an issue. One test laboratory and one academia representative saw no effect on R&D costs.

Research and development costs	Type of respondent	Total
Very negative effect	A business association	1
	A security services provider	1
	An airport operator	1
	Large enterprise (more than 250 employees)	1
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Very negative effect Total		**7**
Negative effect	A business association	3
	A national administration	1
	A non governmental organisation	1
	A security services provider	2
	A test laboratory	1
	An airport operator	4
	Large enterprise (more than 250 employees)	6
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Negative effect Total		**20**
No effect	A national administration	3
	A test laboratory	1
	An academic institution or think tank	1
	Large enterprise (more than 250 employees)	1
No effect Total		**6**
Positive effect	A national administration	4
Positive effect Total		**4**
Grand Total		**37**

- **Competition with US competitors** - 72,97% of the respondents answered either with very negative effect or negative effect. The majority of the participants (all industry except one, airport operators, business association, test labs, NGO) saw this as a problem. National administrations were divided. The security services provider representative did not identify this as a problem.

Competition with US competitors	Type of respondent	Total
Do not know	A business association	1
	A national administration	1
	A test laboratory	1
Do not know Total		**3**
Very negative effect	A security services provider	1
	An airport operator	1
	Large enterprise (more than 250 employees)	5
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Very negative effect Total		**8**
Negative effect	A business association	3
	A national administration	2
	A non governmental organisation	1
	A security services provider	1
	A test laboratory	1
	An academic institution or think tank	1
	An airport operator	4
	Large enterprise (more than 250 employees)	3
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Negative effect Total		**19**
No effect	A national administration	2
	A security services provider	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
No effect Total		**4**
Positive effect	A national administration	2
Positive effect Total		**2**
Very positive effect	A national administration	1
Very positive effect Total		**1**
Grand Total		**37**

- **Time to market of equipment** - 64,86% of the respondents answered either with very negative effect or negative or negative effect. The majority of the participants (all industry except one, airport operators, business association, test labs, NGO) saw this as a problem. The majority of national administrations and all test labs did not see this as a problem.

Time to market of equipment	Type of respondent	Total
Do not know	A business association	1
Do not know Total		**1**
Very negative effect	A business association	1
	A national administration	1
	A security services provider	1
	Large enterprise (more than 250 employees)	3
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	3
Very negative effect Total		**10**
Negative effect	A business association	2
	A non governmental organisation	1
	A security services provider	1
	An airport operator	5
	Large enterprise (more than 250 employees)	4
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Negative effect Total		**14**
No effect	A national administration	3
	A security services provider	1
	A test laboratory	1
	Large enterprise (more than 250 employees)	1
No effect Total		**6**
Positive effect	A national administration	4
	A test laboratory	1
	An academic institution or think tank	1
Positive effect Total		**6**
Grand Total		**37**

B. Significant problem

- **Commercialisation costs** - 59,46% of the respondents answered either with very negative effect or negative effect. It should be noted that 27% of the respondents (airport operators NGO, national administrations) did not have an opinion on this matter. All Industry and test labs did however identify this as a problem.

Commercialisation costs	Type of respondent	Total
Do not know	A business association	1
	A national administration	2
	A non governmental organisation	1
	A security services provider	1
	An airport operator	5
Do not know Total		**10**
Very negative effect	A business association	1
	A security services provider	1
	Large enterprise (more than 250 employees)	2
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
Very negative effect Total		**5**
Negative effect	A business association	2
	A national administration	2
	A test laboratory	2
	An academic institution or think tank	1
	Large enterprise (more than 250 employees)	6
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	4
Negative effect Total		**17**
No effect	A national administration	1
	A security services provider	1
No effect Total		**2**
Positive effect	A national administration	2
Positive effect Total		**2**
Very positive effect	A national administration	1
Very positive effect Total		**1**
Grand Total		**37**

C. Negligible problem

- **Passenger and staff security** - 29,73% of the respondents answered either with very negative effect or negative effect. Over 50% of the respondents did not see any effect on passenger and staff security.

Passenger and staff security	Type of respondent	Total
Do not know	A business association	1
	A national administration	1
	An airport operator	1
Do not know Total		**3**
Very negative effect	Large enterprise (more than 250 employees)	2
Very negative effect Total		**2**
Negative effect	A national administration	1
	A security services provider	2
	An academic institution or think tank	1
	Large enterprise (more than 250 employees)	4
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Negative effect Total		**9**
No effect	A business association	3
	A national administration	4
	A non governmental organisation	1
	A security services provider	1
	A test laboratory	1
	An airport operator	4
	Large enterprise (more than 250 employees)	2
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	3
No effect Total		**20**
Positive effect	A national administration	1
Positive effect Total		**1**
Very positive effect	A national administration	1
	A test laboratory	1
Very positive effect Total		**2**
Grand Total		**37**

- **Training of services personnel** - 18,92% of the respondents answered either with very negative effect or negative effect. Over 70% stated that this has no effect.

Training of services personnel	Type of respondent	Total
Do not know	A national administration	1
	An airport operator	1
	Large enterprise (more than 250 employees)	1
Do not know Total		**3**
Very negative effect	Large enterprise (more than 250 employees)	2
Very negative effect Total		**2**
Negative effect	A business association	1
	A test laboratory	1
	Large enterprise (more than 250 employees)	2
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Negative effect Total		**5**
No effect	A business association	3
	A national administration	6
	A non governmental organisation	1
	A security services provider	3
	A test laboratory	1
	An academic institution or think tank	1
	An airport operator	4
	Large enterprise (more than 250 employees)	3
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	3
No effect Total		**26**
Positive effect	A national administration	1
Positive effect Total		**1**
Grand Total		**37**

- **Use of airport space** - 13,51% of the respondents answered either with very negative effect or negative effect. Nearly 80% of the respondents did not see any effect, including all airport operators.

Use of airport space	Type of respondent	Total
Do not know	A national administration	2
	Large enterprise (more than 250 employees)	1
Do not know Total		**3**
Very negative effect	Large enterprise (more than 250 employees)	2
Very negative effect Total		**2**
Negative effect	Large enterprise (more than 250 employees)	2
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Negative effect Total		**3**
No effect	A business association	4
	A national administration	6
	A non governmental organisation	1
	A security services provider	3
	A test laboratory	2
	An academic institution or think tank	1
	An airport operator	5
	Large enterprise (more than 250 employees)	3
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	3
No effect Total		**29**
Grand Total		**37**

- **Passenger flow** - Facilitation of screening process - increasing throughput - 13,51% of the respondents answered either with very negative effect or negative effect. Over 60% of the respondents did not see any effect, including all airport operators.

Passenger flow - Facilitation of screening process - increasing throughput	Type of respondent	Total
Do not know	A business association	1
	A national administration	3
	An airport operator	1
	Large enterprise (more than 250 employees)	3
Do not know Total		**8**
Very negative effect	Large enterprise (more than 250 employees)	2
Very negative effect Total		**2**
Negative effect	A security services provider	1
	Large enterprise (more than 250 employees)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Negative effect Total		**3**
No effect	A business association	3
	A national administration	4
	A non governmental organisation	1
	A security services provider	2
	A test laboratory	2
	An academic institution or think tank	1
	An airport operator	4
	Large enterprise (more than 250 employees)	2
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	3
No effect Total		**23**
Positive effect	A national administration	1
Positive effect Total		**1**
Grand Total		**37**

1.2.Problems related to the laboratories

The Commission had identified a series of possible issues related to the laboratories currently used in the ECAC CEP system for the testing of aviation screening equipment. A set of five questions was thus developed to inquire on the regulations and the functioning of the laboratories. Two of these questions were restricted to industry representatives:

- **The accreditation of laboratories** - the ECAC CEP laboratories are currently not accredited on EU level but merely adopted by ECAC on the basis of proposals from member states. These laboratories do therefore not issue legally binding certifications, but only non-binding test results. Over 84% of the respondents agreed that this legal uncertainty should be amended and that test laboratories should be accredited at an EU level. The majority of the participants (all industry except one, business associations, one test lab and 6 out of seven airport operators) saw this as a problem.

Do you believe that test laboratories should be accredited on a EU level?	Type of respondent	Total
No response	A national administration	1
	A security services provider	1
	An airport operator	2
No response Total		**4**
Do not know	A non governmental organisation	1
	An airport operator	1
Do not know Total		**2**
No	A national administration	1
	A test laboratory	1
	Large enterprise (more than 250 employees)	1
No Total		**3**
Yes	A business association	4
	A national administration	6
	A security services provider	2
	A test laboratory	1
	An academic institution or think tank	1
	An airport operator	2
	Large enterprise (more than 250 employees)	7
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	4
Yes Total		**28**
Grand Total		**37**

- **Quality control of the laboratories** – 67% of the respondents agreed that the laboratories should be audited on a regular basis. A relatively high number (24%, i.e. the nine "blanks") of respondents did not reply to this question

Do you believe the test laboratories should be regularly audited	Type of respondent	Total
Do not know	A business association	2
	A national administration	1
Do not know Total		**3**
Yes	A business association	2
	A national administration	5
	A security services provider	2
	A test laboratory	1
	An academic institution or think tank	1
	An airport operator	2
	Large enterprise (more than 250 employees)	7
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	4
Yes Total		**25**
(blank)	A national administration	2
	A non governmental organisation	1
	A security services provider	1
	A test laboratory	1
	An airport operator	3
	Large enterprise (more than 250 employees)	1
(blank) Total		**9**
Grand Total		**37**

- **Membership in the ECAC CEP system** – the membership to the ECAC CEP system is not an entirely open process, but based on a selection made by ECAC. On the question if the current situation hindered them in becoming an ECAC - CEP test laboratory, three respondents answered with yes.

Has the current situation hindered you in becoming a ECAC - CEP test laboratory?	Type of respondent	Total
(blank)	A business association	1
	A national administration	1
	A non governmental organisation	1
	A security services provider	2
	An airport operator	2
	Large enterprise (more than 250 employees)	1
(blank) Total		**8**
Do not know	A business association	2
	A national administration	1
	An academic institution or think tank	1
	An airport operator	2
	Large enterprise (more than 250 employees)	3
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Do not know Total		**11**
No	A business association	1
	A national administration	6
	A security services provider	1
	A test laboratory	2
	An airport operator	1
	Large enterprise (more than 250 employees)	2
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
No Total		**15**
Yes	Large enterprise (more than 250 employees)	2
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Yes Total		**3**
Grand Total		**37**

1.3. Questions reserved solely for industry

A set of questions was developed aimed at gaining an insight on the specific problems encountered by the aviation screening technology Industry. These questions focussed on the role and functioning of the ECAC CEP laboratories.

- **Availability of laboratories** – the Commission had received indications that the limited number of ECAC CEP laboratories led to bottleneck situations, where the demand in tests exceeds the testing capacities of the labs. This assessment was confirmed by the consultation, eight out of the eleven industry representatives stated that the availability of laboratories and the time to test were not adequate.

Do you think the availability of test laboratories and time to test appointment is adequate	Type of respondent	Total
Do not know	Large enterprise (more than 250 employees)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Do not know Total		**2**
No	A business association	1
	Large enterprise (more than 250 employees)	4
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
No Total		**8**
Yes	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Yes Total		**1**
Grand Total		**11**

- **Choosing the laboratory** – the ECAC CEP system does not allow the manufacturers to choose the laboratory in which they want to test their equipment. Nine out of the eleven industry respondents expressed their interest in choosing their laboratory.

INDUSTRY ONLY 2.8.2 Do you think it would be important to be able to choose test laboratory?	Type of respondent	Total
Do not know	Large enterprise (more than 250 employees)	1
Do not know Total		**1**
No	Large enterprise (more than 250 employees)	1
No Total		**1**
Yes	A business association	1
	Large enterprise (more than 250 employees)	3
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	4
Yes Total		**9**
Grand Total		**11**

1.4.Conclusion

The public consultation provided a series of concrete answers to the initial assessments of the Commission on the problems that affect the certification system of aviation screening equipment. A clear distinction could be made between the largely acknowledged problems which should be addressed by the Commission and the problems which had only a very marginal support and could be discarded.

The central problems identified by the respondents concern mainly the negative effects due to the fragmented regulatory framework of the certification system on: - the commercialisation of aviation screening equipment (I.e. research and development costs, the efficiency of the certification process, legal certainty and the time to market of equipment); and - the external dimension (I.e. harmonisation with third countries and competition with the US).

It should be underlined that these assessments were made by the majority of stakeholders be they SME, large industry, test laboratories or business associations. The only group respondents which expressed some reservations were the representatives from national administrations

A similar concern was expressed by the respondents with regards to the current system of the CEP testing laboratories. A strong majority of the respondents agreed that the status of the laboratories should be consolidated by accrediting them on an EU level. At the same time, the respondents also stated that these laboratories should be audited on a regular basis.

The questions on the laboratories targeted solely for industry representatives confirmed this interest in a restructuring of the laboratory system. Industry stakeholders judged the current availability and the time to test of the laboratories to be inadequate. They also expressed their interest in being able to choose their test laboratory.

Issues like to use of airport space, the training of personnel, passenger and staff security and the passenger flow were deemed to be largely irrelevant. The need for the Commission to act on these aspects is thus secondary.

2. Assessment of the Options

An essential part of this consultation was assessing the support for the five policy options developed by the Commission in the context of this initiative.

The options provided to the respondents were as follows:

1. "Baseline scenario" - The Commission would not launch any dedicated policy initiative to harmonise the certification procedures for aviation screening equipment.

2. "Recommendation" - The Commission would issue a recommendation to Member States to mutually accept each other's national approval systems or to rely on the common evaluation process of ECAC, provided that EU laboratories undertaking performance testing respect certain requirements.

3. "Legislation" - The Commission would propose legislation on product certification and compliance testing principles and procedures in order to ensure full compliance with EU security performance standards adopted under Regulation (EC) 300/2008.

> **3.1. The "directive-based approach"** is characterised by a set of detailed specifications which are laid out in the directive itself.
>
> **3.2. The "standards-based approach"** is not based on specifications with the same level of detail as in 3.1. This approach is based on the so called "new approach", which focuses on essential requirements written in general terms.
>
> **3.3. The "centralised approach"**, whereby product certification would be done centrally by an EU agency, such as the European Aviation Safety Agency, which already certifies all EU commercial aircraft.

The participants were asked to assess which of the five options listed above would allow the Commission to achieve the following objectives:

- Ensuring the optimal level of security for European airports and citizens
- Increasing the capacity of technology to adapt to emerging threat scenarios
- Increasing the facilitation[38]
- Reducing research and development costs
- Reducing commercialisation costs
- Ensuring passenger safety
- Improving passenger flow
- Facilitating the training of security officers
- Optimising the use of airport space
- Fostering the harmonisation with third countries, for example the US
- Providing better guidance to procurers
- Improving mutual trust in Member States' aviation security in view of "one stop security"
- Reducing time to market of equipment
- Influencing the competition with non-EU suppliers
- Simplifying the procurement process of aviation screening equipment for airport operators or their procurement agencies

The respondents were asked to rate (from: very negative, negative, no effect, positive, very positive) the efficiency of the five action on these objectives. For the analysis of this consultation, these replies where translated into a points system, from -2 for very negative, over 0 for no effect, to 2 for very positive.

The sums of the answers were then used to rank of the options based on the following system: majority of very negative = --, majority of negative = -, no effect = 0, positive = +, very positive = ++. The results of the assessment of the options by the respondents have been listed in the table below. *Criteria and weighting of the options*

The respondents were asked to rate (from: very negative, negative, no effect, positive, very positive) the efficiency of the five policy options on various aspects. For the analysis of this consultation, these replies where translated into a points system, from -2 for very negative, -1 for negative, 0 for no effect, +1 for positive, +2 for very positive.

[38] Facilitation is a specific terminology used in the aviation sector which covers the aviation security process. See: http://www2.icao.int/en/AVSEC/FAL/Pages/default.aspx

"Within the civil aviation community, facilitation is of interest to four major groups: Contracting States, air transport operators, airports and customers. States are primarily interested in achieving full compliance with their laws and regulations, whereas operators are focused on increasing productivity by minimizing the costs of operational delays and administrative procedures. Airports view facilitation as a means to reduce congestion in passenger terminals and cargo sheds. The fourth group, air transport customers (i.e. passengers and cargo shippers), wants to proceed through airports with minimal delay and difficulty."

Five of the questions are of particular importance for the realisation of the objectives; these questions have been highlighted in **bold.** These questions address issues which have been highlighted as very significant problems in the context of the questions on the problem definition.

- Reduce research and development costs?
- Reduce commercialisation costs?
- Foster the harmonisation with third countries, for example the US?
- Reduce time to market of equipment?
- Influence the competition with non-EU suppliers?

Three of the questions were met with very limited responses from the stakeholders; these questions have been highlighted in *italic*. On the following questions one third of the participants answered "do not know".

- Increase the facilitation?
- Ensure passenger safety?
- Improve passenger flow?

Ranking of the options

	Which of the afore-mentioned options do you believe has the greatest potential to:	**Options**				
		3.1	3.2	3.3.1	3.3.2	3.3.3
Questions	**Reduce research and development costs?**	--	+	++	+	++
	Reduce commercialisation costs?	--	-	++	+	++
	Foster the harmonisation with third countries, for example the US?	--	--	++	-	++
	Reduce time to market of equipment?	--	-	+	0	++
	Influence the competition with non-EU suppliers?	--	-	++	+	++
	Ensure the optimal level of security for European airports and citizens?	--	-	+	+	++
	Increase the capacity of technology to adapt to emerging threat scenarios?	-	0	+	-	++
	Facilitate the training of security officers?	-	-	+	+	+
	Optimise the use of airport space?	-	-	-	+	++
	Provide better guidance to procurers?	--	-	++	0	++
	Improve mutual trust in Member States' aviation security in view of “one stop security"?	--	-	++	+	++
	Simplify the procurement process of aviation screening equipment for airport operators or their procurement agencies?	--	-	++	+	++
	Increase the facilitation?	-	+	+	+	++
	Ensure passenger safety?	-	+	+	+	+
	Improve passenger flow?	-	+	+	+	+

Conclusion

Three of the questions were met with very limited responses from the stakeholders. On the questions referring to: *increase the facilitation*, *ensure passenger safety* and *improve passenger flow* one third of the participants answered "do not know".

On the question referring to *Optimise the use of airport space* the large majority of the respondents replied that none of the options would have any noticeable effect.

The large majority of the respondents preferred option 3.3 "the centralised approach" followed by 3.1 "directive-based approach" and 3.2 "standards-based approach". The different stakeholder group gave a largely homogeneous reply on these questions. No major discrepancies among the various groups were identified.

The centralised approach (3.3) was judged to have the highest potential for a positive impact on all questions. The respondents favoured this option independently of their background.

A similar support by the stakeholders was, albeit to a slightly lesser extent, expressed on option 3.1, the directive based approach. The respondents judged it to have a potentially very positive impact on seven and positive on seven further questions. The only aspect where this option was judged to have a potential negative impact concerned the optimisation of airport space.

The standards based approach received a less positive response from the participants. This option was not judged to have a very positive impact on any of the questions. On four questions, the respondents gave this option either negative or "no effect" marks.

Options 1 "Baseline scenario" and 2 "Recommendation" were judged to have either ineffective or even to be harmful to the current situation.

The baseline scenario, i.e. not launching any initiative to improve the current situation, was judged to have a negative impact on all the areas addressed by the questions.

The recommendation was judged to have a moderately positive impact on only four aspects: increasing the facilitation, reducing research and development costs, ensuring passenger safety and improving passenger flow.

3. Technical questions on the certification procedures

- Should a harmonised certification procedure be based on the approval of a sample item (type-approval) or of each item produced? – 92% answered with yes. No respondent disagreed.

Should a harmonised certification procedure be based on the approval of a sample item (type-approval) or of each item produced?	Type of respondent	Total
No opinion	A business association	2
	A national administration	1
No opinion Total		**3**
Yes	A business association	2
	A national administration	7
	A non governmental organisation	1
	A security services provider	3
	A test laboratory	2
	An academic institution or think tank	1
	An airport operator	5
	Large enterprise (more than 250 employees)	8
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	4
Yes Total		**34**
Grand Total		**37**

- Should manufacturers be informed about the details of the outcome of the tests so as to facilitate the improvement of the equipment? – 89% answered with yes. Only one national administration and one test laboratory disagreed with this assessment.

Should manufacturers be informed about the details of the outcome of the tests so as to facilitate the improvement of the equipment?	Type of respondent	Total
Do not know	A business association	1
Do not know Total		**1**
No	A national administration	1
	A test laboratory	1
No Total		**2**
Yes	A business association	3
	A national administration	7
	A non governmental organisation	1
	A security services provider	3
	An academic institution or think tank	1
	An airport operator	5
	Large enterprise (more than 250 employees)	8
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	4
Yes Total		**33**
Grand Total		**36**

- Should manufacturers be informed about the testing procedures for equipment? – 83 % answered with yes. National administrations were divided on this issue. All other respondents were in favour.

Should manufacturers be informed about the testing procedures for equipment?	Type of respondent	Total
No	A national administration	4
No Total		**4**
No opinion	A business association	2
No opinion Total		**2**
Yes	A business association	2
	A national administration	4
	A non governmental organisation	1
	A security services provider	3
	A test laboratory	1
	An academic institution or think tank	1
	An airport operator	5
	Large enterprise (more than 250 employees)	8
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	4
Yes Total		**30**
Grand Total		**36**

- According to you, are on-site acceptance tests necessary? – 73 % answered with yes. Only two national administrations and two large enterprises disagreed. It should be underlined that all airport operators were in favour of these on-site tests.

According to you, are on-site acceptance tests necessary?	Type of respondent	Total
No	A national administration	2
	Large enterprise (more than 250 employees)	2
No Total		**4**
No opinion	A business association	3
	Large enterprise (more than 250 employees)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
No opinion Total		**6**
Yes	A business association	1
	A national administration	6
	A non governmental organisation	1
	A security services provider	3
	A test laboratory	2
	An academic institution or think tank	1
	An airport operator	5
	Large enterprise (more than 250 employees)	5
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Yes Total		**27**
Grand Total		**37**

- Do you believe that on-site acceptance tests should be harmonised? – 70% answered with yes. Several respondents (25%) did however disagree, among which four airport operators.

Do you believe that on-site acceptance tests should be harmonised?	Type of respondent	Total
No	A business association	1
	A national administration	1
	A non governmental organisation	1
	A test laboratory	1
	An airport operator	4
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
No Total		**9**
No opinion	A security services provider	1
No opinion Total		**1**
Yes	A business association	3
	A national administration	7
	A security services provider	2
	A test laboratory	1
	An academic institution or think tank	1
	An airport operator	1
	Large enterprise (more than 250 employees)	7
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	3
Yes Total		**26**
Grand Total		**36**

Conclusion

The five questions on technical aspect of the certification process showed general support for EU action, the approval rates ranging from 70% to 92%. Some restrictions were however expressed concerning two questions.

Two questions gather unambiguous support by the participants. The respondents showed strong support for a sample item/type approval based certification system (92% approval). A similar support was expressed regarding the need to provide details on the outcome of the tests to the manufacturers (89% approval).

The need for on-site acceptance test was also supported by a large majority (73%). A noticeable aspect is the relatively high number of "no opinion" responses from industry representatives.

On the question referring to "Informing the manufacturers on the testing procedures", the national administrations were evenly split in their responses (four against and four in favour). The general response was however favourable at 83% approval.

The need to harmonise on site acceptance test was met with the lowest support from the respondents at 70%. It should be underlined that four out of the five airport operators were among the 25% of respondents who disagreed with this question.

4. The role of the European Civil Aviation Conference (ECAC)

- The ECAC - CEP system should be considered in the establishment of an EU-wide harmonised certification system for aviation screening equipment. Do you agree/disagree? – 95% of the respondents answered either with strongly agree (64%) or agree (30%), only 5% disagreed. The only respondents who did not agree were representatives from security services providers.

The ECAC - CEP system should be considered in the establishment of an EU wide harmonised certification system for airport screening equipment. Do you agree/disagree?	Type of respondent	Total
Agree	A business association	2
	A national administration	1
	An academic institution or think tank	1
	An airport operator	1
	Large enterprise (more than 250 employees)	4
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Agree Total		**11**
Disagree	A security services provider	1
Disagree Total		**1**
Strongly agree	A business association	2
	A national administration	7
	A non governmental organisation	1
	A security services provider	1
	A test laboratory	2
	An airport operator	4
	Large enterprise (more than 250 employees)	4
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Strongly agree Total		**24**
Strongly disagree	A security services provider	1
Strongly disagree Total		**1**
Grand Total		**37**

- The work by the ECAC technical groups on developing standards should be retained in an EU-wide harmonised certification system. Do you agree/disagree? 95% of the respondents answered either with strongly agree (64%) or agree (30%), only 5% disagreed. The only respondent who did not agree was a representative from a security services provider.

The work by the ECAC technical groups on developing standards should be retained in an EU wide harmonised certification system. Do you agree/disagree?	Type of respondent	Total
Agree	A business association	2
	A national administration	1
	A security services provider	1
	An airport operator	1
	Large enterprise (more than 250 employees)	4
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Agree Total		**11**
Disagree	A security services provider	1
Disagree Total		**1**
Do not know	An academic institution or think tank	1
Do not know Total		**1**
Strongly agree	A business association	2
	A national administration	7
	A non governmental organisation	1
	A security services provider	1
	A test laboratory	2
	An airport operator	4
	Large enterprise (more than 250 employees)	4
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Strongly agree Total		**24**
Grand Total		**37**

- If you answered "agree/strongly agree" to question 5.2, what do you think ECAC's liability should be? – full liability: 19%, limited liability: 27%, no liability: 5%, do not know 40%. No stakeholder group had a clear opinion on this issue.

What should be the liability of ECAC?	Type of respondent	Total
Do not know	A business association	4
	A non governmental organisation	1
	A security services provider	1
	A test laboratory	1
	An airport operator	5
	Large enterprise (more than 250 employees)	1
	Medium enterprise (between 50 and 249 employees, turnover less than €50 million)	1
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	1
Do not know Total		**15**
Full liability	A national administration	2
	Large enterprise (more than 250 employees)	3
	Micro or small enterprise (fewer than 49 employees, turnover less than €10 million)	2
Full liability Total		**7**
Limited liabily	A national administration	5
	A security services provider	1
	A test laboratory	1
	Large enterprise (more than 250 employees)	3
Limited liabily Total		**10**
No liability	A national administration	1
	Large enterprise (more than 250 employees)	1
No liability Total		**2**
Grand Total		**34**

Conclusion

The consultation showed a clear support for the central role of ECAC. Over 90% of the respondents concluded that the ECAC - CEP system should be considered in the establishment of an EU-wide harmonised certification system for aviation screening equipment and that the work by the ECAC technical groups on developing standards should be retained in an EU-wide harmonised certification system.

The question related to the liability of ECAC was not met with a clear response by the participants. A considerable part of the respondents (40%) did not have an opinion on this matter, only 27 % of the respondents judged a limited liability to be suitable and less than 20% expressed their support for a full liability.

Summary of the Workshop

The Workshop "Discussion on a possible Commission initiative on Harmonisation of the Certification of Aviation Screening Equipment" took place on 25 September 2013 in Brussels.

The aim of the Workshop was:

- to present to the stakeholders the latest studies that were conducted in the field of aviation screening equipment as well as the initial findings of the public consultation that was carried out on last spring; and
- to give each stakeholder group the possibility to present their view on a possible harmonisation of the certification of aviation screening equipment.

The presentations given during the Workshop were split in two sessions. The first three presentations were given either by Commission officials or by a contractor of the Commission. The last three presentations were given by each central stakeholder group, which had the opportunity to present their view on the possible Commission initiative.

The first three presentations were given by:

- A representative of the external contractor who wrote the *"Study on Civil Security R&D in major third countries"*. The focal point of this presentation was the Cost-Benefit-Analysis of the different policy options envisaged by the Commission.

- A representative of the JRC, who presented the outcome of their study on *"Detection Requirements and Testing Methodologies for Aviation Security Screening Devices in the EU and EFTA".*

- A representative of DG Enterprise and Industry (European Commission), who presented a detailed assessment of the public consultation.

The three presentations of the second session were given by:

- Industry representative: the Chairman of the Civil Aviation Security Working Group of the European Organisation for Security (EOS).

- ECAC representative: the Chairman, Management Group of the Common Evaluation Process of Security Equipment, European Civil Aviation Conference (ECAC)

- End-users representative: a Senior Manager of the Aviation Security, Airports Council International (ACI) Europe.

The main statements brought forward by industry were:

- The lack of a harmonised certification system in the EU has led to a massive confusion among both the supply and the demand side.

- The lack of a single, recognisable EU certification system and label has proven to be a strong handicap when competing with TSA approved, US companies in emerging third countries. One specific example was given by an industry representative who stated that, while competing in a tender against a US company for a contract in Venezuela, he was negatively affected by the legal uncertainty of the ECAC system. The value as a sales argument of a non-binding testing system which is not recognised across the EU suffers a great deal against the well know and legally binding certification of the TSA.

- Further criticism by industry of the ECAC CEP system also concerned the following aspects:

    - The ECAC service responsible for the CEP is understaffed, this created bottlenecks and leads to delays in testing. One industry representative stated that he had to wait over 6 months to get a testing appointment, which in turn delays the commercialisation;

    - The results of the tests are not communicated in a timely manner;

- There are differences between the labs, both in terms of quality, price and speed of testing.
- It was also mentioned on several occasions that the amount and detail of information on the results of the testing procedures diverged considerably from one lab to the other, which can lead to disadvantages among the manufacturers;

- At the same time, the large majority of the industry representatives stated that the ECAC CEP system has been considerably improved over the last years and that it should be integrated into a harmonised EU-wide certification system.

The main statements brought forward by ECAC were:

- The results are given to the Member States not to manufacturers. In consideration of some criticism received from the manufacturers, ECAC is currently working to improve the efficiency and the timeliness of the testing system
- ECAC is working in collaboration with the American TSA. In terms of standards it is not needed that the EU ones are the same than the TSA ones but it would still be to converge towards common standards
- The CEP system is open to all 44 ECAC Members as a tool to be used for the national certification. It has to be stressed that this is not as a certification system per se.

The main statements brought forward by end-users/ACI were:

- Legal certainty of the certification testing is needed.
- A harmonisation of the EU certification system with the US TSA certification system should be achieved.
- The ECAC CEP system is good but needs to be improved as the testing process is not fast enough and the results of the test are not published in a timely manner.
- At today, EU airports are not allowed to buy equipment that is not mentioned on the ECAC website. This means that such equipment is already out of the market.
- It is highly recommendable to have testing lab's accreditation system at the EU level
- ACI would like to be involved in the testing process also to ensure the inclusion of operational requirements in the testing methodologies

Conclusion by the ENTR Chairman of the workshop (Graham Willmott)

- A main conclusion of the workshop was the convergence of the results of the studies presented during the first session, in terms of both problematic issues and potential solutions.
- The initial findings of the online public consultation that we have launched in the first half of 2013 are in line with the gaps and, overall, the needs of the main stakeholders

in this area who have provided us with their views on what is the desirable way forward in the area of the certification of aviation screening equipment

- It should be underlined that all participants agreed that ECAC should continue to play a central role in a possible future harmonised certification system for aviation screening equipment. A possible involvement of EASA was not mentioned by any of the participants.

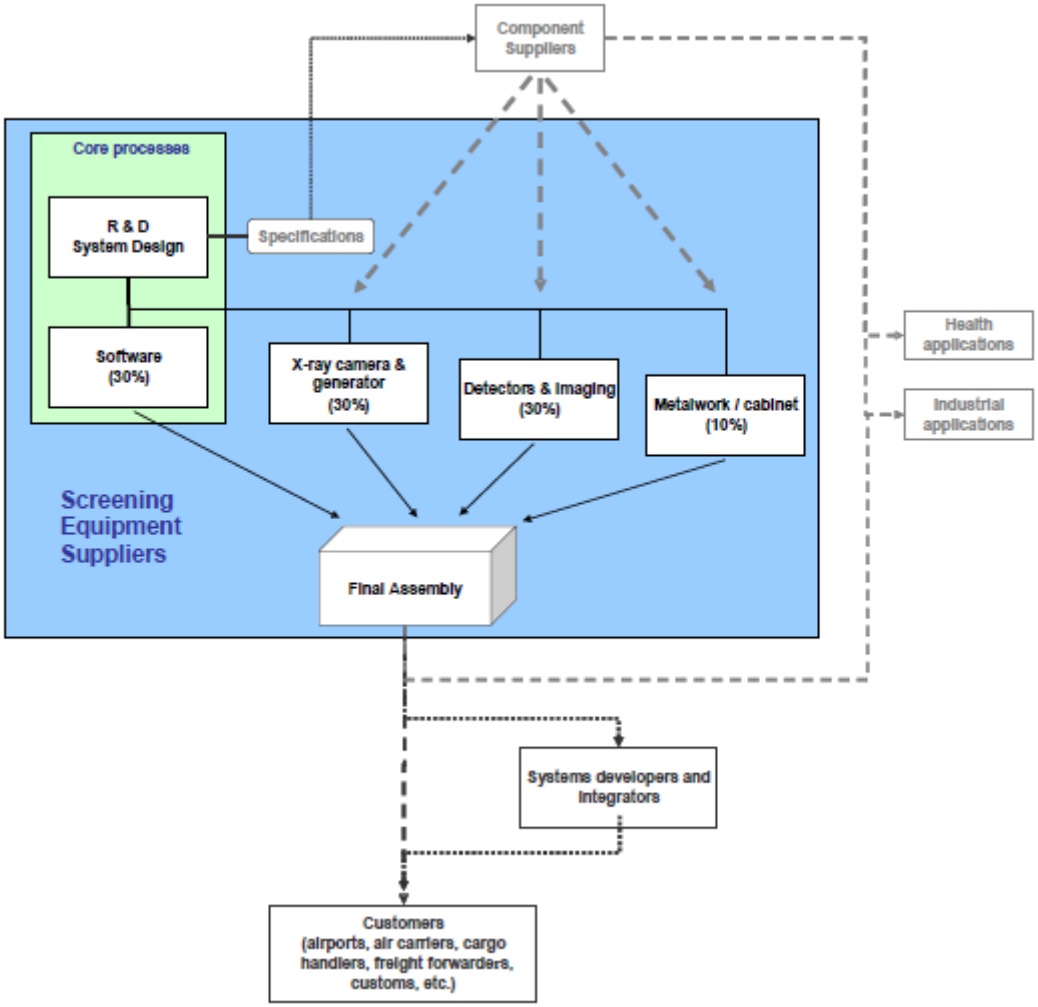
ANNEX 5: PROCEDURE FOR TESTING THE AVIATION SECURITY EQUIPMENT

No	Description	Actors involved
1	A manufacturer develops a new configuration of equipment that is intended for the European market.	Manufacturer
2	As a part of the development process and before submitting the equipment for ECAC-CEP tests at CEP test centres through the ECAC secretariat, manufacturers may (or may not) invest in "private testing". This is done in order to generate technical feedback on performance of the equipment against real threats.	Manufacturer; Private testing entity
3	When the manufacturer decides to submit the configuration to approval testing through the ECAC CEP, the manufacturer contacts the ECAC Secretariat and asks for the allocation to a CEP-Test centre and a time slot. Manufacturers may require access to the regulatory detection requirement standards from their Member State authorities. The actual ECAC Common Testing Methodologies are partly classified and not disclosed in their entirety. However, an unclassified summary is provided through ECAC.	Manufacturer; ECAC Secretariat
4	The ECAC Secretariat collects requests and provides them to the ECAC CEP Management Group. The ECAC CEP-MG consist of (representatives of) all test centres allocated to the CEP as well as the allocating Member States.	ECAC Secretariat; ECAC CEP Management Group
5	The ECAC CEP Management Group convenes 4 times per year and manages urgent issues through other means of communication. The requests are scrutinized on so-called Simulator Retest feasibility and matched to available testing slots at test centres in the next 2 Quarters. Principles applied include test centre rotation, quality control, capacity allocation maximization, fairness, cost reduction. The results is provided to the ECAC secretariat.	ECAC Management Group; ECAC secretariat
6	The ECAC Secretariat informs the manufacturer on the time slot and the test centre to which the configuration is allocated.	ECAC Secretariat; Manufacturer
7	The Manufacturer enters into a contract with the allocated test centre.	Manufacturer, test Centre
8	According to contact the Manufacturer transports its equipment to the contracted ECAC-CEP test centre. Usually a limited and defined preliminary phase is carried out as first part of the test, after which the Manufacturer is contacted and consulted with regard to continuation, in order to minimize costs in case of expected failure. The Manufacturer is allowed to change the configuration once. If there is agreement on continuation, the Test Centre progresses to conduct the test in full. The ECAC-CEP Test Centre applies the ECAC CTMs, and applies the established local safety procedures and quality standards in place. The Manufacturer does not witness the test but remains stand-by to apply maintenance if needed.	ECAC-CEP Test Centre; Manufacturer

	Test are regularly visited by staff of other Test Centres a per quality control measures. After conclusion of the test the Test Centre provides an oral so-called debrief to the Manufacturer where, in addition to the outcome (pass or fail against an applicable standard) a maximum of information feedback is provided, without disclosing the detailed CTM nor classified data.	
9	After the testing is completed, the ECAC-CEP Test Centre provides a report in standardized format (included in the CTM) to the ECAC Secretariat (level 1 and level 2 report). This includes pass or fail against applicable EU standards, as well as more detailed results. The raw data (level 3 report) remain the property of the MS who allocated the Test Centre to the CEP process. At the next convention of the EDCAC CEP Management Group the group discusses the details of all completed tests and decides on endorsement. When the results are endorsed the Manufacturer receives a closing letter. When a standard is passed the equipment configuration is published on the website.	ECAC-CEP Test Centre; ECAC CEP Management Group; ECAC Secretariat; Manufacturer

ANNEX 6: STYLISED SUPPLY/VALUE CHAIN FOR AVIATION SECURITY SCREENING EQUIPMENT

Based on the example of x-ray based systems. Numbers in parentheses indicate the approximate breakdown of cost elements in final equipment.



ANNEX 7: OVERVIEW ON THE IMPACTS ON COMPETITIVENESS OF EU BUSINESSES

1. "Baseline scenario"

Cost and price competitiveness	Positive	Negative
Cost of inputs	n/a	n/a
Cost of capital	n/a	n/a
Cost of labour	n/a	n/a
Other compliance costs (e.g. reporting obligations)s		Yes
Cost of production, distribution, after-sales services		Yes
Price of outputs (e.g. price controls)	n/a	n/a
Capacity to innovate		
Capacity to produce and bring R&D to the market		Yes
Capacity for product innovation		Yes
Capacity for process innovation (including distribution, marketing and after-sales)		Yes
Access to risk capital	n/a	n/a
International competitiveness		
Market shares (single market)		Yes
Market shares (external markets)		Yes
Revealed comparative advantages		

2. A recommendation

Cost and price competitiveness	Positive	Negative
Cost of inputs	n/a	n/a
Cost of capital	n/a	n/a
Cost of labour	n/a	n/a
Other compliance costs (e.g. reporting obligations)s	Yes?	
Cost of production, distribution, after-sales services	Yes?	
Price of outputs (e.g. price controls)	n/a	n/a
Capacity to innovate		
Capacity to produce and bring R&D to the market	Yes?	
Capacity for product innovation	Yes?	
Capacity for process innovation (including distribution, marketing and after-sales)	Yes?	
Access to risk capital	n/a	n/a
International competitiveness		

Market shares (single market)	Yes?	
Market shares (external markets)	Yes?	
Revealed comparative advantages		

3.1. The "old approach"

Cost and price competitiveness	**Positive**	**Negative**
Cost of inputs	n/a	n/a
Cost of capital	n/a	n/a
Cost of labour	n/a	n/a
Other compliance costs (e.g. reporting obligations)s	Yes	n/a
Cost of production, distribution, after-sales services	Yes	
Price of outputs (e.g. price controls)	n/a	n/a
Capacity to innovate		
Capacity to produce and bring R&D to the market	Yes	
Capacity for product innovation	Yes	
Capacity for process innovation (including distribution, marketing and after-sales)	Yes	
Access to risk capital	n/a	n/a
International competitiveness		
Market shares (single market)	Yes	
Market shares (external markets)	Yes	
Revealed comparative advantages		

3.3. The "centralised approach"

Cost and price competitiveness	**Positive**	**Negative**
Cost of inputs	n/a	n/a
Cost of capital	n/a	n/a
Cost of labour	n/a	n/a
Other compliance costs (e.g. reporting obligations)s	Yes	
Cost of production, distribution, after-sales services	Yes	
Price of outputs (e.g. price controls)	n/a	n/a
Capacity to innovate		
Capacity to produce and bring R&D to the market	Yes	
Capacity for product innovation	Yes	
Capacity for process innovation (including distribution, marketing and after-sales)	Yes	
Access to risk capital	n/a	n/a

International competitiveness	
Market shares (single market)	Yes
Market shares (external markets)	Yes
Revealed comparative advantages	

Discarded Option 3.2 "new approach"

Costs

The reduction of the need to test multiple times a single piece or 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, as not all the costs are directly related to the price of the certification as such (e.g. the shipping of the equipment).[39] The loss of income for the testing laboratories should therefore be under 0.5 million Euros per year.

Results of the public consultation for option 3.2

The standards based approach received a less positive response from the participants than the regulation based approach. Regarding key aspects it was judged to have a positive impact on research and development costs, Reduce commercialisation costs, and the competition with non-EU suppliers.

This option was however not judged to have a very positive impact on any of the issues addressed by the consultation. Stakeholders judged it to have negative impact on the key aspect of fostering the harmonisation with third countries and a possible increase of the capacity of technology to adapt to emerging threat scenarios. Similarly, the impact of option 3.2 on the reduction of time to market of equipment and providing better guidance to procurers was estimated to be non-existent.

3.2. The "new approach",

Cost and price competitiveness	**Positive**	**Negative**
Cost of inputs	n/a	n/a
Cost of capital	n/a	n/a
Cost of labour	n/a	n/a
Other compliance costs (e.g. reporting obligations)s	Yes	
Cost of production, distribution, after-sales services	Yes	
Price of outputs (e.g. price controls)	n/a	n/a
Capacity to innovate		
Capacity to produce and bring R&D to the market	Yes	
Capacity for product innovation	Yes	
Capacity for process innovation (including distribution, marketing and after-sales)	Yes	
Access to risk capital	n/a	n/a
International competitiveness		

[39] See SER3Co study, chapter 3.2.4

Market shares (single market)	Yes
Market shares (external markets)	Yes
Revealed comparative advantages	

ANNEX 8: BACKGROUND INFORMATION ON THE LEGAL IMPLICATIONS OF THE POLICY OPTIONS

The old approach

The old approach is for instance used in the case of motor vehicles. It is worth providing a small overview of how this system functions in this product sector.

Illustrative example

The EC Whole Vehicle Type-Approval (EC WVTA) system has applied to motor vehicles and motorcycles on a mandatory basis since January 1998 and June 2003, respectively. As a result, these categories of vehicles must comply with all the relevant EC type-approval directives in order to be placed on the market.

The currently applicable Framework Directive on type-approval of motor vehicles (2007/46/EC) makes EC WVTA mandatory for all categories of motor vehicles (passenger cars, buses, coaches and trucks) and their trailers. The implementation of this directive is enforced in accordance with a time-frame extending from 2009 to 2014, depending on the category.

The Directive provides for the Member States to take appropriate measures at two stages:

1. Ex-ante assessment: Before granting approval, the approval authority must ensure that all the relevant tests provided for in the relevant Regulatory Acts listed in Annex IV to that Directive have been carried out by a designated 'technical service' . Furthermore, before granting type-approval, the approval authority must verify that adequate arrangements for ensuring conformity of production (see ex-post surveillance below) have been made by the manufacturer.

2. Ex-post surveillance: after giving approval, the approval authority must verify that the production arrangements of the manufacturer continue to be adequate. This verification must be carried out in accordance with the procedures set out in the Directive, and, where appropriate, with the specific provisions of the relevant Regulatory Acts listed in Annex IV to that Directive. This procedure may be carried out on manufacturers' technical equipment and control programs, but may also be extended to the actual testing of selected production samples.

Before providing approval, the approval authority must ensure that all the relevant tests provided for in the type approval legislation have been carried out by a technical service.

The approval authority of each Member State must send to the approval authority of the other Member States a copy of the vehicle type-approval certificate for each vehicle type which it has approved, refused to approve or withdrawn.

For vehicle types to which EC whole vehicle type approval (EC-WVTA) applies, each Member State shall register or permit the sale and entry into service of new vehicles only if they are accompanied by a valid certificate of conformity (CoC).

A certificate of conformity is, in effect, a statement by the manufacturer that the vehicle conforms to the vehicle type that has been granted the relevant EC WVTA. Other Member States cannot refuse to register vehicles if they are accompanied by a valid CoC, proving their compliance with Community legislation.

The new approach

The new approach, is not based on specifications as detailed as under the old approach. The new approach focuses on essential requirements written in general terms. Product legislation is restricted to the requirements necessary to protect the public goals of health and safety. Examples for these requirements include for instance the capacity of the testing lab to handle dangerous materials or the need for real or virtual testing etc. The technical specifications under the new approach are elaborated by the responsible European Standardisation Organisations (CEN/CENELEC and ETSI). These standards would be publicly available as in the mandate of the Standardisation Organisations.

This certification would be based on a third party certification. A self-certification by the manufactures can be excluded given the sensitive nature of aviation screening equipment.

New approach legislation is based on the following principles:

- Harmonisation is limited to essential requirements.
- Only products fulfilling the essential requirements may be placed on the market and put into service.
- Compliance with harmonised standards, the reference numbers of which have been published in the Official Journal of the European Communities and which have been transposed into national standards, provides a presumption of conformity with the corresponding essential requirements.
- Application of harmonised standards or other technical specifications remains voluntary and manufacturers are free to choose any technical solution that complies with the essential requirements.

Adoption of new approach legislation

- New approach directives are based on Article 114 of the EU Treaty, and are adopted according to the co-decision procedure provided for in Article 294 of the EU Treaty.
- Adopted new approach directives are published in the L series of the Official Journal of the European Communities. Commission proposals for new approach directives are published in the C series of the Official Journal.

Transposition of new approach legislation

- New approach directives are total harmonisation directives: the provisions of these directives supersede all corresponding national provisions.
- New approach directives are addressed to the Member States, which have an obligation to transpose them into their national legislation as appropriate.
- National laws, regulations or administrative provisions, which transpose the directive, shall contain a reference to the directive in question or shall be accompanied by such a reference on the occasion of their official publication.
- National laws, regulations or administrative provisions, which are adopted and published in order to transpose a directive, must be communicated to the Commission.

The "centralised approach

The "centralised approach", whereby the certification would be done centrally by an EU agency, such as for example the European Aviation Safety Agency (EASA), which already today certifies centrally all EU commercial aircrafts.

Under this approach, there would be an EU-wide procedure for the authorisation of aviation screening equipment, where there is a single application, a single evaluation and a single authorisation throughout the European Union.

Illustrative example

An example for such a centralised approach is the European Medicines Agency's (EMA). The European Medicines Agency is an EU agency for the evaluation of medicinal products. The European Medicines Agency's main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency is responsible for the scientific evaluation of applications for European Union (EU) marketing authorisations for human and veterinary medicines in the centralised procedure.

Under the centralised procedure, pharmaceutical companies submit a single marketing-authorisation application to the EMA. Once granted by the European Commission, a centralised marketing authorisation is valid in all European Union (EU) Member States, as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway. By law, a company can only start to market a medicine once it has received a marketing authorisation.