European Union Aviation Safety Agency

Comment-Response Document (CRD) 2022-09

RELATED NPA: 2022-09 — RELATED OPINION: No 01/2023 — RMT.0161 (Subtask 1)

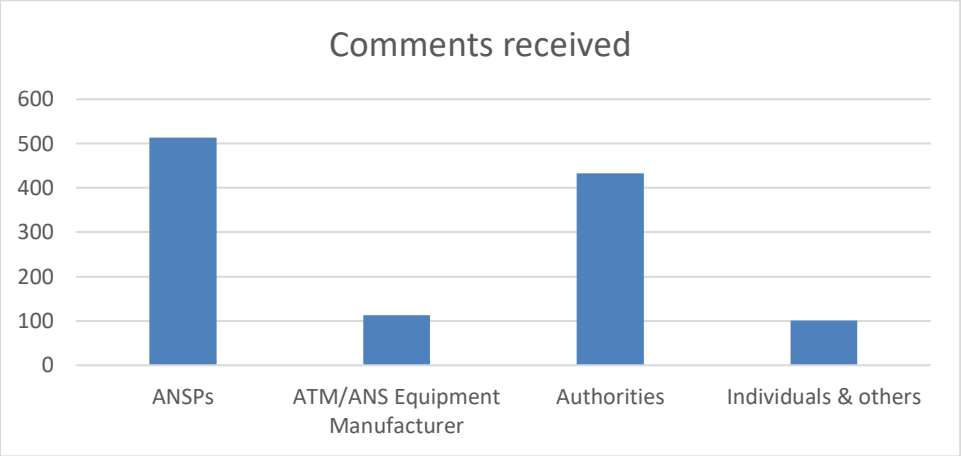
31.1.2023

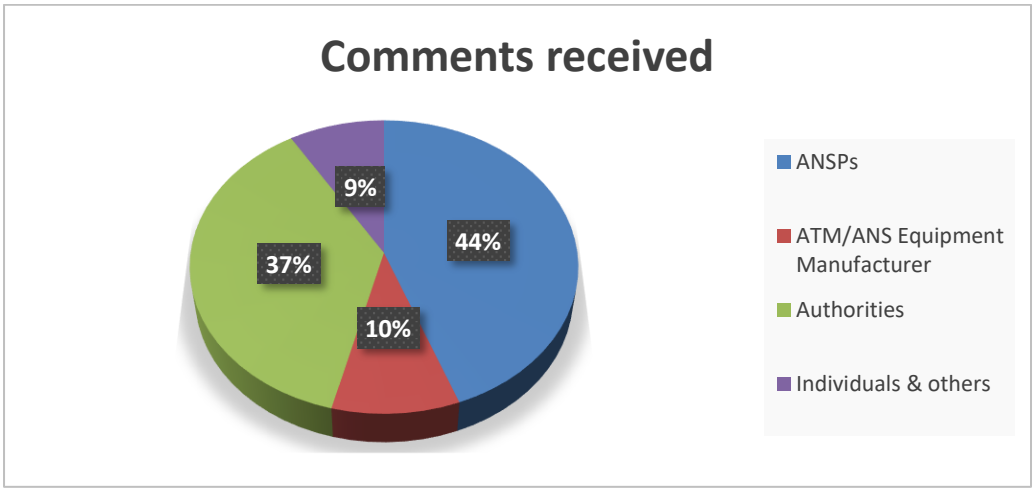
Table of contents

1. Summary of the outcome of the consultation

NPA 2022-09[1], on the establishment of a regulatory framework on the conformity assessment of certain ATM/ANS systems and ATM/ANS constituents (ATM/ANS equipment) as well as on the approval of organisations involved in its design and/or production, received 1 160 comments from 50 commenters.

513 comments were submitted by air navigation service providers (ANSPs), 433 comments by national competent authorities (NCAs), 113 comments by ATM/ANS equipment manufacturers, 50 comments by individuals, and 51 comments by other sectors of industry, as shown in the bar chart below:

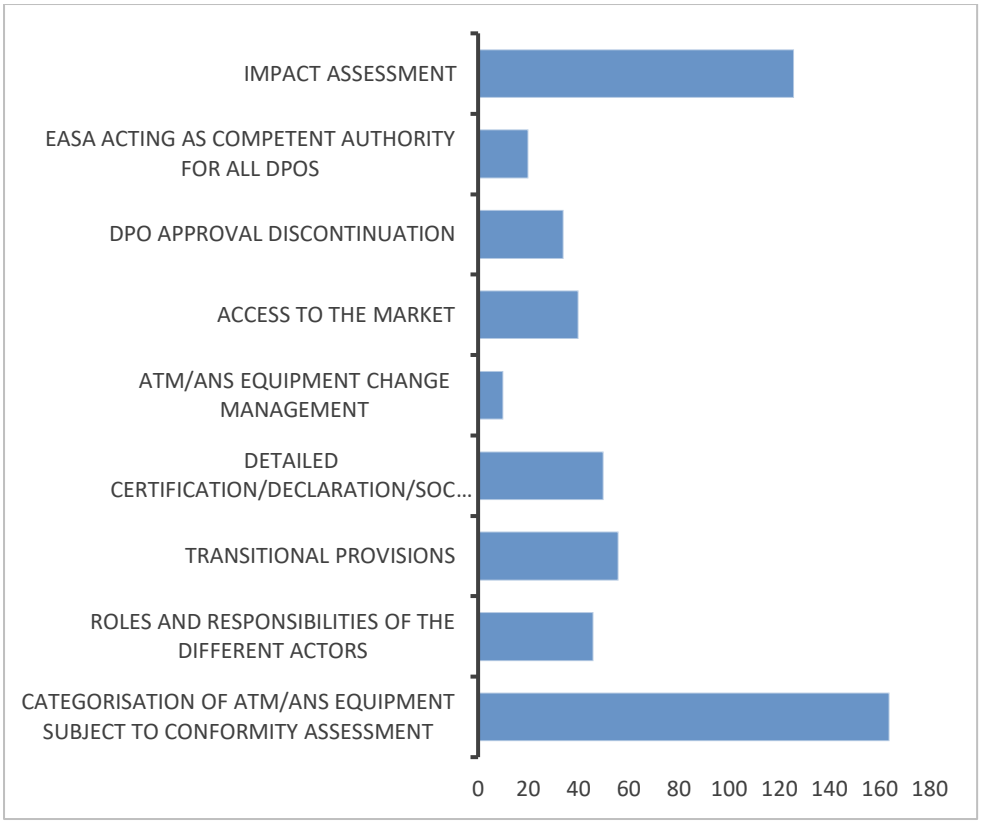




The comments received were grouped and aggregated into topics for their processing by EASA. This approach is reflected in this CRD as well as in the structure of the discussions with various groups of experts during the period October 2022 – December 2022.

The chart below presents the most commented topics, while the rest of the comments were of general nature, expressing preferences, proposing editorial changes or correcting references and asking for clarifications:

[1] NPA 2022-09 - Establishment of a regulatory framework on the conformity assessment of ATM/ANS systems and ATM/ANS constituents (ATM/ANS equipment) (Subtask 1) | EASA (europa.eu)



Furtehrmore, the comments received per section of the NPA are as follows:

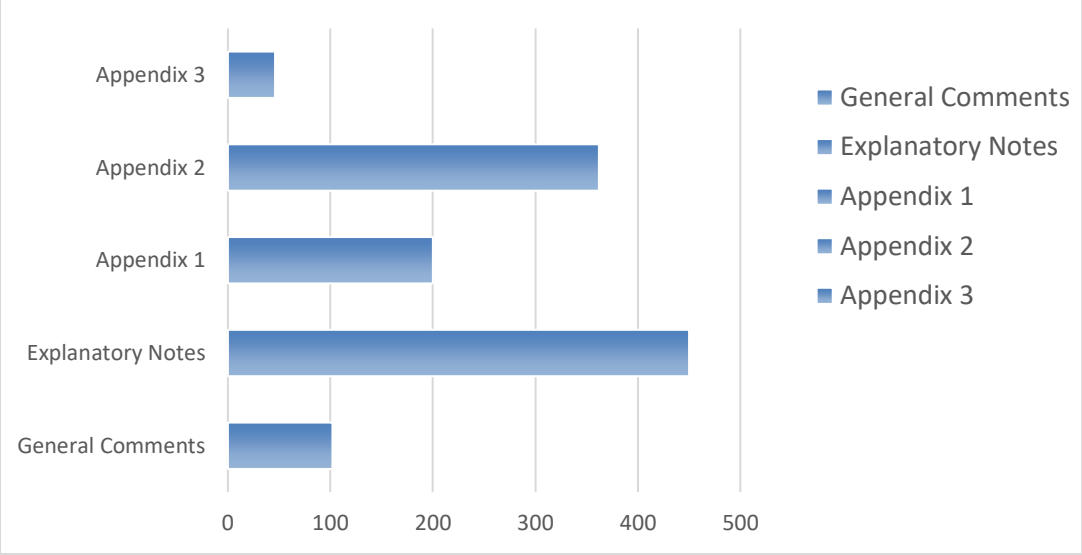
— General comments (102 comments)

— Explanatory Note, including the Impact assessment (450 comments)

— Appendix 1: DRAFT COMMISSION IMPLEMENTING REGULATION (EU) …/... laying down technical requirements and administrative procedures for the approval of organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents (200 comments)

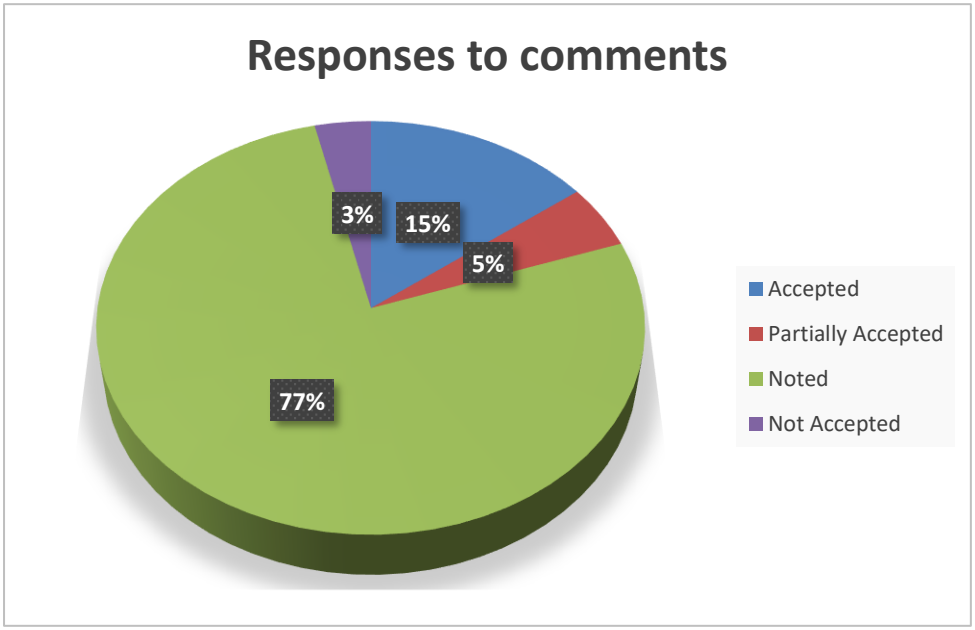
— Appendix 2: DRAFT COMMISSION DELEGATED REGULATION (EU) …/... laying down common technical requirements and administrative procedures for the certification and declaration of compliance of the design of ATM/ANS systems and ATM/ANS constituents (362 comments)

— Appendix 3: DRAFT COMMISSION IMPLEMENTING REGULATION (EU) …/... amending Implementing Regulation (EU) 2017/373 as regards the conformity assessment of ATM/ANS systems and ATM/ANS constituents (46 comments)



After considering the comments received, the final draft regulatory text is available in EASA Opinion No 01/2023[2].

Most of the comments received have been either noted or accepted. The pie chart below shows the statistics on comment acceptance by EASA:



[2] Opinions | EASA (europa.eu)

2. Conclusions of the comment review by topic

2.1. Categorisation of ATM/ANS equipment subject to conformity assessment

Description of the issue

NPA 2022-09 proposed that certain ATM/ANS equipment should be subject of conformity assessment, establishing three different attestation instruments considering the nature and the risk of the operation or functionality enabled by the particular equipment:

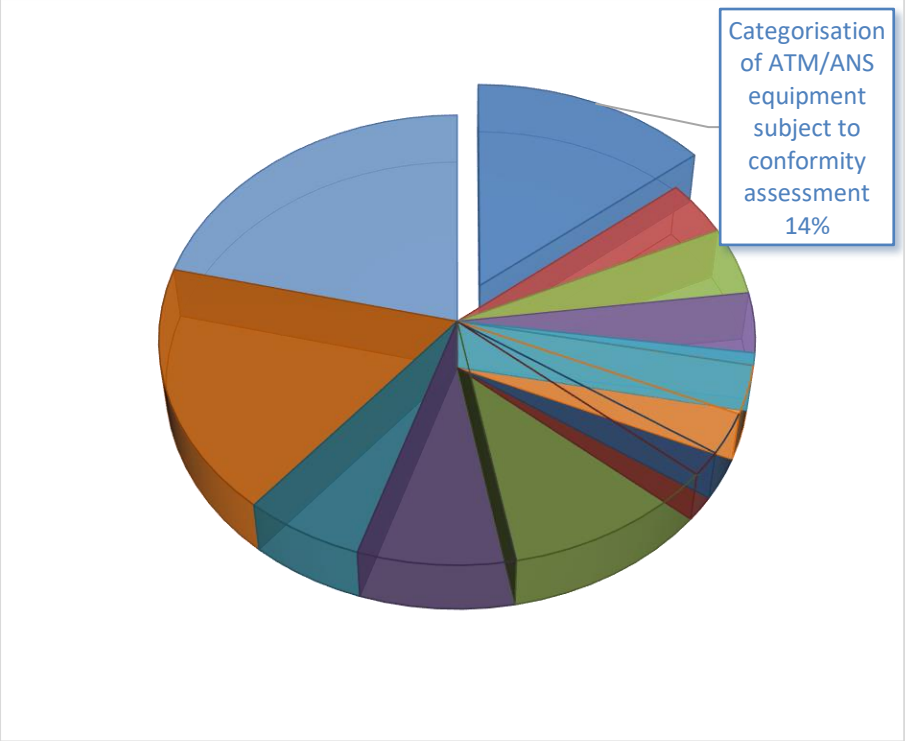
— certification of certain ATM/ANS equipment based on detailed certification specifications (Article 4);

— declaration by an approved organisation involved in the design and/or production of ATM/ANS equipment for other designated ATM/ANS equipment based on detailed declaration specifications (Article 5); and

— statement of compliance (SoC) by the ATM/ANS provider confirming that the equipment complies with the technical standards listed in detailed specifications (Article 6).

Articles 4, 5 and 6 of the proposed delegated act included the high-level criteria aimed to categorise the equipment subject to the different attestation methods. The detailed specifications and AMC are intended to provide further details on the applicability of the different instruments.

A considerable number of the comments submitted to NPA 2022-09 requested additional explanations on the type of ATM/ANS equipment subject to certification and to declaration as well as to statement of compliance. In some cases, the commenters have also indicated that supplementary details should be provided at the level of the delegated act, and not only in the AMC and detailed specifications. Additional requests frequently raised within this set of comments are: clarification about the relevant attestation instrument for equipment supporting certain ATM/ANS services, e.g. MET, ATFM; proportionality between the conformity assessment activities and the relevance of safety and interoperability for each type of equipment; terminology used in the proposal and the explanatory note.



Considerations and way forward

The feedback provided has highlighted the need to provide additional details about the categorisation at the level of the delegated regulation, which will establish the basis to be complemented by the content of the detailed specifications and the acceptable means of compliance. While fully understanding the need for more clarity and certainty as regards categorisation of the type of ATM/ANS equipment subject to conformity assessment, EASA sees also a need to maintain a commensurate balance between the binding regulation on the one hand, and the detailed specifications and the acceptable means of compliance on the other hand; this in order not to hinder industrial innovation in any way.

The addition to the delegated regulation will take the form of an annex determining the equipment subject to the different attestation requirements, looking at which ATM/ANS functions and services are supported. For clarity and legal consistency reasons, the list mirrors the list included in Annex VIII to Regulation (EU) 2018/1139. The text in Articles 4, 5 and 6 of the proposed delegated regulation will be accordingly adapted, as presented below.

#	Point 3 of Annex VIII ER EASA BR (EU) 2018/1139	Article 4 Certifiable ATM/ANS Eq.	Article 5 Declarable ATM/ANS Eq.	Article 6 SoC ATM/ANS Eq.
1.	Airspace management (=ASM)			X
2.	Air traffic flow management (=ATFM)			X
3.	Air traffic services (ATS), in particular flight data processing systems, surveillance data processing systems and human-machine interface systems	X		
4.	Communications (=COM) including ground-to-ground/space, air-to-ground and air-to-air/space communications			
	4a. Ground-to-ground communications		X	
	4b. Air-to-ground communications	X		
5.	Navigation (=NAV)		X	
6.	Surveillance (=SUR)		X	
7.	Aeronautical Information services (=AIS)			X
8.	Meteorological services (=MET)			X

This additional material defines the envelop of ATM/ANS services and functions subject to conformity assessment requirements, i.e. equipment supporting any other ATM/ANS functions or services not included in the table is not subject to dedicated conformity assessment requirements.

It has to be noted that not all equipment supporting a particular service or function as per the table above will be subject to conformity assessment, as the criteria contained in Articles 4 and 5 of the proposed delegated act are kept. The criteria contained in these articles identify the critical functionalities that drive the need for conformity assessment. In the case of equipment supporting air traffic services, the criteria established require that in the case of equipment that comprises functionalities for controller–pilot communications, the separation of aircraft and the prevention of collisions is subject to certification, while any other equipment used in the frame of ATS provision is not. For instance, equipment simply using processed data to give further support and alleviation to ATCO tasks but not comprising any of the functionalities above.

The basic principles underpinning the proposal are not changed; the functionalities and delivered services are the focus when deciding which ATM/ANS elements are to be certified or declared by the

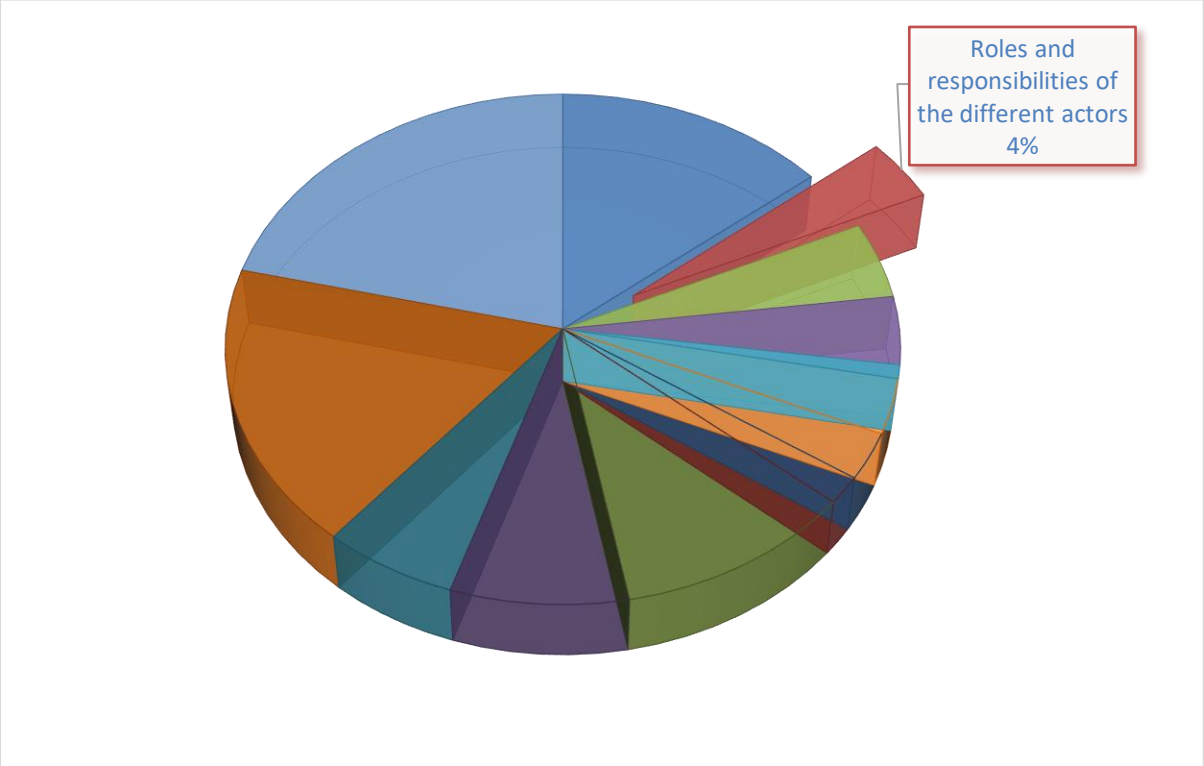
design and production organisation. The detailed specifications and acceptable means of compliance, currently under development through Subtask 3 of RMT.0161, will be developed following these principles, avoiding being unnecessarily prescriptive about the underlying architecture, and recognising the relevance of data services in the future evolution of the ATM system.

2.2. Roles and responsibilities of the different actors

Description of the issue

One of the main novelties proposed by NPA 2022-09 is the distinction between the responsibilities of the ATM/ANS providers and those of the organisations involved in the design and/or production of ATM/ANS equipment.

A considerable number of comments received address the allocation of responsibilities requiring further explanation and providing inputs to be considered in the next phases of RMT.0161. In particular, the following aspects are commented: overall responsibility to ensure safe service provision; impact in terms of liability for the manufacturers; distribution of responsibilities in particular in relation with the installation, operational integration and maintenance of the equipment; impact on the relation between the ATM/ANS provider and its suppliers; facilitation of ATM/ANS providers compliance with their safety and safety support responsibilities; how manufacturers in the supply chain of ATM/ANS equipment are affected by the proposal.



Considerations and way forward

EASA has assessed the feedback provided arriving to the conclusion that no adaptation was needed at the level of the proposed delegated and implementing regulations. Many of the questions and requests for clarification highlight areas that will be further addressed by dedicated AMC/GM.

In this section a set of considerations are included, intended to provide additional explanation to the allocation of responsibilities and answering the main elements in the questions received:

— In accordance with the proposed framework, the DPO will be responsible to specify, design and produce the equipment. The equipment will need to be certified or the DPO will need declare that the equipment is compliant with the relevant essential requirements through the demonstration of compliance with the detailed specifications, depending on the type of equipment. ATM/ANS equipment will then be integrated into the functional system of an ATM/ANS provider.

  The proposal does not have any impact on the overall responsibility of the ATM/ANS providers to ensure that any change to their functional system is introduced only after a safety or safety support assessment has been completed and provides assurance via a complete argument that the service will behave as specified in the relevant operational environment. The safety assessment and safety support assessment requirements are contained in Regulation (EU) 2017/373 and are not modified by this proposal. When an ATM/ANS provider, and in particular an ATSP, buys/procures equipment to be introduced in its functional system, it will continue to ensure that all safety (support) requirements allocated to the equipment are met.

  Under Subtask 3 of RMT.0161, additional AMC/GM to Regulation (EU) 2017/373 will be developed addressing how the new types of evidence of compliance (equipment certificates or declarations by DPO) should/can be used by the ATM/ANS provider when consolidating their safety evidence and presenting it to the competent authorities.

— In relation with the legal involvement of manufacturers in the design and/or production of ATM/ANS equipment, it is important to highlight that the proposal does not introduce any relevant changes. Under the current framework, the manufacturer issues an EC declaration (respectively Declaration of Conformity or Declaration of Suitability for Use, depending on the existence of not of Community Specifications) in accordance with Regulation (EU)2018/1139 and the SES IOP Regulation (EC) No 552/2004. With this declaration, the manufacturer assumes the responsibility that the equipment complies with the essential requirements established in Annex VIII to the Baisc Regulation. Essentially, the same approach will be maintained under the proposed framework. The main difference of the proposed framework is that compliance with the essential requirements will be ensured based on detailed specifications adopted by EASA.

  From a more general perspective it can be highlighted that the Basic Regulation (EU) 2018/1139 and its implementing rules do not regulate liability aspects, and therefore they cannot increase the risk of liability.

— Responsibilities in relation with the installation, operational integration and recurrent maintenance (following the instructions/manuals provided by the design and production organisation) of the equipment are in the sphere of the ATM/ANS provider. These activities are already covered by the provisions of Regulation (EU) 2017/373 and are not affected by the proposal.

  An upgrade to equipment is normally associated with a change to the functions, including the methods and technology used. These changes/upgrades might affect the demonstration of compliance of the equipment with the applicable detailed specifications, with the potential of having an impact on the validity of the certificates or declarations. Therefore, they will be in the

sphere of responsibility of the design and production organisation. This does not prevent that certain changes could be implemented by the user of the equipment (ATM/ANS provider) but always under the control and conditions prescribed by the DPO, following approved change management processes.

— The proposal aims to distribute the responsibilities for the demonstration of compliance of systems and constituents with the essential requirements among the ATM/ANS providers and the organisations involved in the design and production of the equipment. Therefore, it will have a certain impact on how the relations between the ATM/ANS providers and their suppliers are organised, as covered in the impact assessment presented in NPA 2022-09.

  However, the proposal does not regulate or prescribe any particular type of arrangements between the ATM/ANS providers and the organisations involved in the design and production of the equipment, as long as those arrangements allow both organisations to demonstrate compliance with the respective regulatory requirements.

— Some comments and questions address the perceived need to provide supporting material to the ATM/ANS providers on how to discharge their safety and safety support responsibilities.

  Considering this feedback, EASA will develop in the frame of Subtask 3 of RMT.0161 AMC/GM to address how the ATM/ANS providers should present to the relevant competent authority the evidence of the conformity assessment, as well as the verification and validation activities in the frame of the installation and integration in their functional system.

— A few questions refer to how manufacturers in the supply chain of ATM/ANS equipment manufacturers could be affected by the proposal.

  A DPO approval is required in order for an organisation to be able to apply for the certification or to declare the design compliance of ATM/ANS equipment. This will be required only for a subset of functionalities supporting the provision of ATM/ANS services, and the organisation taking responsibility for the design and production compliance will need to be approved as DPO. Suppliers of a DPO will not need to be approved, but the integration/use of the subcontracted products and/or services to produce the ATM/ANS equipment will be under the control/management system of the approved DPO.

2.3. Transitional provisions

Description of the issue

The proposed delegated act in NPA 2022-09 includes transitional provisions, acknowledging that a new framework cannot be introduced immediately, as some of its building blocks require time to be implemented; most notably, the design and production organisations will need to be approved; time will be required for the the equipment certification or for the demonstration and documentation of compliance with the relevant detailed specifications for the declaration. Besides those periods for the demonstration of compliance, all entities will need to adapt their organisation in terms of both processes and the necessary resources.

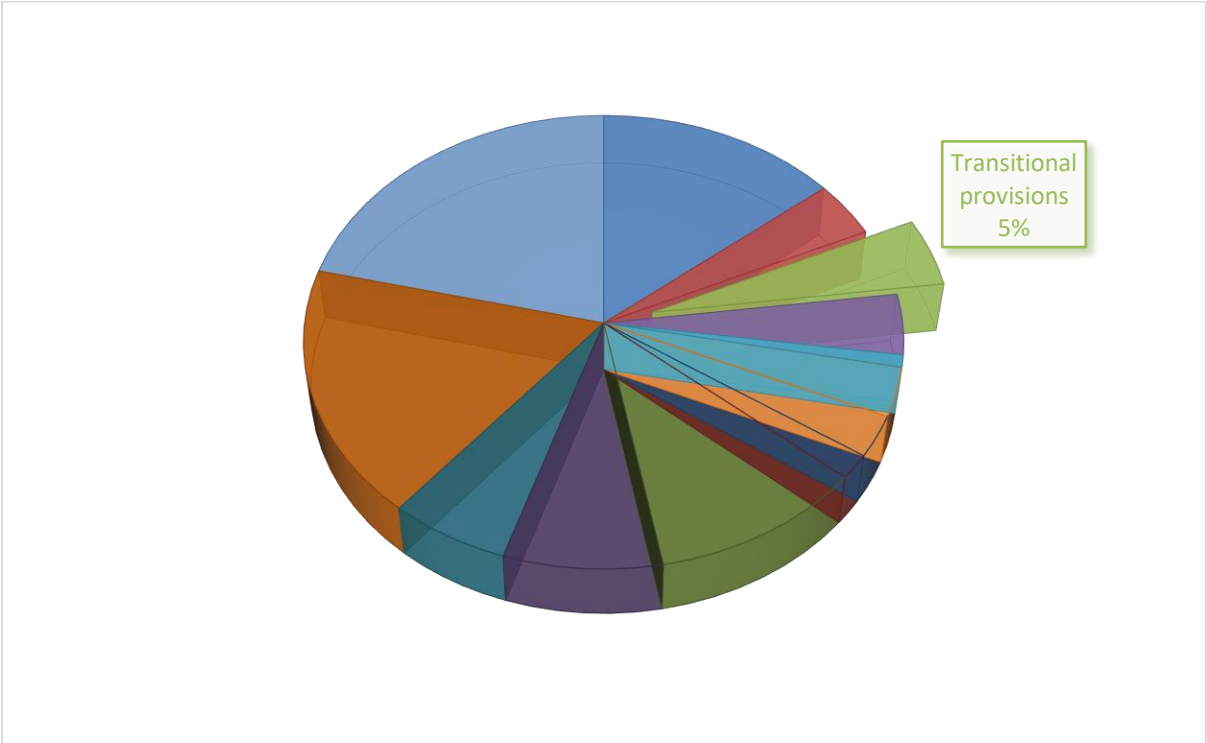
In summary, the key features of the transitional provisions proposed in NPA 2022-09 are:

— A transition period of 5 years is envisaged.

— Equipment already in service before the new framework would apply and holding an EC Declaration of Verification (DoV) will be considered compliant with the requirements subject to an evaluation by EASA in the latest part of the transition *period [5 years from the entry into force of the regulation, i.e. 2028]*.

— Equipment (in the 'certification' and 'declaration' categories) put into operation during the transition period [*5 years from the entry into force of the regulation, i.e. 2028]* might also be attested by the ATM/ANS providers using the equipment. Once the transition period is over, EASA will be required to evaluate that that equipment ensures a level of safety, performance and interoperability equivalent to that resulting from the full application of the delegated act.

— As from the end of the transition period, the attestation evidence for all ATM/ANS equipment to be introduced into service, either new equipment or changes/evolution to already deployed equipment, will need to be fully compliant with the delegated act.



Most of the feedback received to NPA 2022-09 stresses the need to ensure a balanced approach to the transition, avoiding any unintended effects on equipment introduced into service before September 2023, as well as providing a sound platform for the smooth continuation of ongoing developments. A few questions/comments refer to: the length proposed for the transition period [5 years]; the possible continuation of SES IOP declarations scheme; the evaluation by EASA of equipment attested under the transitional arrangements and the arrangements for the information required for such evaluation to be provided to EASA; the need to link the transition period to the availability of the detailed specifications and AMC; as well, a few clarifications and suggestions for the text of the proposed Article 7 (currently Article 8 in Opinion No 01/2023) were received.

Considerations and way forward

EASA has assessed the feedback provided. It has concluded that most of the comments do not require an adaptation of the regulatory text proposed in the NPA, but recommend the preparation of additional guidance material to support the introduction of the new framework. A few slight amendments are introduced in Article 7(3) (currently Article 8(3) in Opinion No 01/2023) aiming to improve the wording and provide additional clarity.

After reflection on the NPA 2022-09 feedback, the following aspects are highlighted:

— Length of the transition period

  A few comments on the NPA point to the necessity to give enough time to the industry to demonstrate compliance with the new requirements, both at organisation and product level. This includes a few requests for the extension of the length of the transition period beyond the proposed 5 years.

  EASA acknowledges that a larger transition period would provide more time to the industry to adapt their processes and demonstrate compliance; however, it would also postpone the expected benefits of the new framework in terms of interoperability and facilitation of the deployment of new technologies necessary for the enhancement of the EATMN performance.

  EASA considers that the proposed 5-year period provides a reasonable balance and enough time for the preparation of all actors, also when considering the typical lifecycles of ATM/ANS equipment.

— On the potential issuance of Declarations of Verification (DoV), Declarations of Conformity (DoC), Declarations of Suitability for Use (DSU) after September 2023, it needs to be highlighted that DoV, DoC and DSU are instruments regulated in the already repealed SES IOP Regulation (EC) No 552/2004, and the transitional provision in the Basic Regulation (EU) 2018/1139 referring to the issuance of these declarations cease to apply on 12 September 2023. Therefore, DoV, DoC or DSU cannot be issued after 12 September 2023.

— The evaluation by EASA of equipment attested under the transitional arrangements was introduced in the proposal as it is understood as a necessary formal step enabling the transfer of the evidence produced, i.e. declarations and technical files, under the repealed SES IOP framework to the new framework. It is acknowledged that this evaluation will require adequate resourcing, compared with the option suggested in the comments to exempt or grandfather in-service equipment.

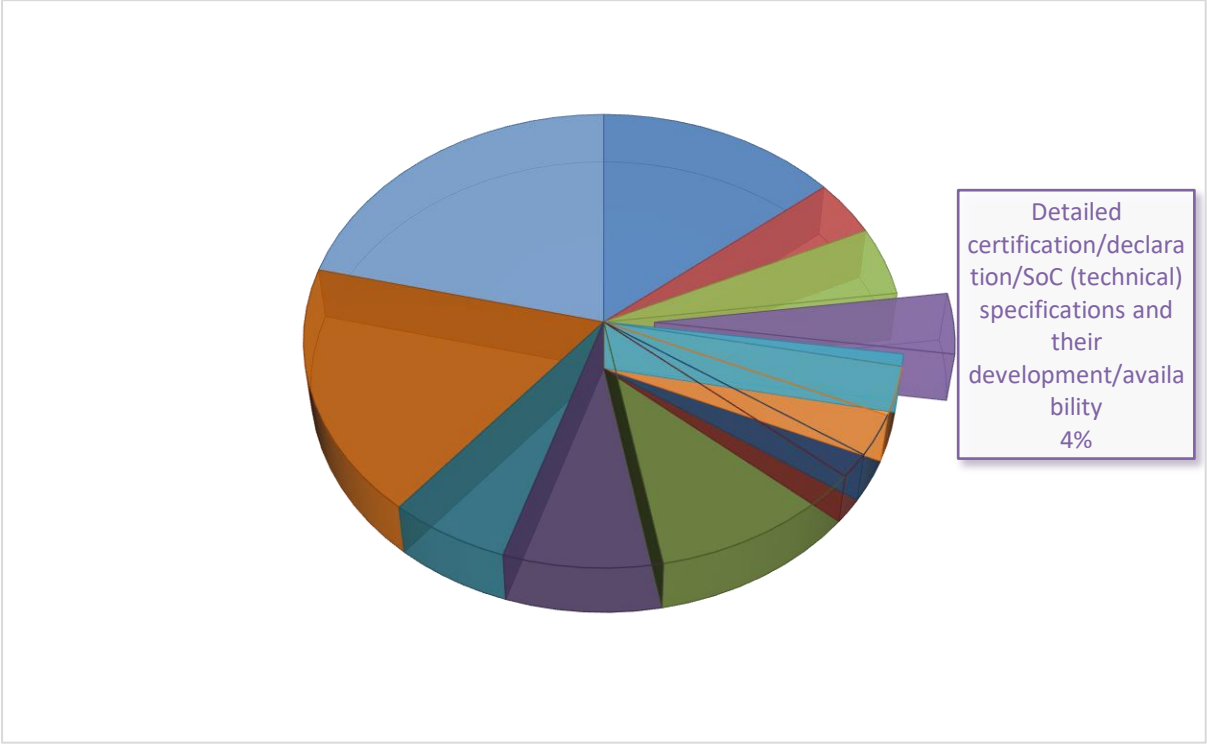
  Regarding the evidence necessary for this evaluation, the proposal requires the authorities responsible for the certification and oversight of ATM/ANS providers to transfer the relevant information to EASA. This provision has been developed considering the workflow and responsibilities in the repealed Regulation (EC) No 552/2004, which required the DoV and technical files to be submitted to the relevant competent authority, also responsible for the review and acceptance of the changes to the functional system introduced by these providers.

— EASA acknowledges the feedback on the need to ensure that, separately to the transitional arrangements in the delegated act, the introduction of detailed specifications and associated AMC would facilitate the appropriate arrangements for their application.

2.4. Detailed certification/declaration/SoC (technical) specifications and their development/availability

Description of the issue

NPA 2022-09 explained broadly the new ATM/ANS equipment conformity assessment principles. Where certification or declaration is required, this will be based on the demonstration of compliance with the relevant detailed certification/declaration specifications. As well, detailed specifications, listing the relevant industry standards, will be developed to support the issuance of Statements of Compliance (SoC). Such specifications will be prepared by EASA in close cooperation with all interested stakeholders, in particular the relevant industry, then followed by an EASA Decision adopting and issuing the respective set of the detailed (certification/declaration/SoC) specifications. Such specifications will provide via a single process the common requirements for the purpose of demonstration of compliance in terms of safety, functionality, interoperability, security and performance as necessary for the European aviation market. Before the publication of such an ED Decision, the proposed specifications will be publicly consulted through a dedicated EASA NPA. EASA will aim at performance- and objective-based specifications and will refer to widely recognised standards published by industry, developed through standards development organisations (SDOs), as far as possible, but obviously this is without prejudicing the outcomes of the public consultation.



Such ATM/ANS equipment specifications were not a part of NPA 2022-09 as they will be developed progressively later, when the actual content of the related regulatory acts concerning the conformity assessment framework are to be adopted and are content-wise more accurately known. Also, in this sense, it is understandable that stakeholders provided further questions and remarks related to the process that will be followed to develop and maintain the certification/declaration/SoC specifications.

In the comments several concerns were expressed on the inclusiveness dimensions of the process to develop the certification/declaration specifications, including also concerns as regards the availability

of the necessary resources by EASA. Some commenters queried about the possibility to support issuing the SoC (Statement of Compliance) against specifications providing for compliance with the essential requirements of the Basic Regulation. Questions were also made concerning the scope of the specifications, in particular whether the necessary requirements on cybersecurity could be included as an element of the single process, as well as concerning the need to be able to promote the much-needed innovation and rapidly emerging technological developments.

Considerations and way forward

EASA has assessed the feedback provided, which in general was regarded to be very helpful also in the context of the next phases of the process of finalising the ATM/ANS equipment conformity assessment framework. EASA has concluded that the big majority of the comments do not require an adaptation of the regulatory text proposed in the NPA but there is a need for clarification of certain essential aspects of the process to develop the certification/declaration/SoC specifications to support successful introduction of the new framework. It is also evident that more clarity and further communication efforts will be needed to ensure the inclusiveness and necessary contribution of the involved stakeholder community.

After reflecton on the NPA 2022-09 feedback, the following aspects can be highlighted:

— Process

  The preparation of the needed certification/declaration/SoC specifications will be based on an open, transparent process which will allow broad stakeholder participation and contributions as well as full transparency via public consultation.

— Scope

  All the necessary requirements (including regarding safety, functionality, interoperability, security and performance) can be contained through a single process in the set of specifications. This would facilitate the process and avoid the risk of overlapping requirements potentially stemming from different regulatory purposes.

— Content of specifications

  Due to the specificities of the ATM domain, including the necessary innovation and emerging technologies, the certification/declaration specifications need to be as far as possible based on performance needs, address system functionalities as well as be of a technology agnostic nature. Also, as far as possible, specifications need to be supported by available industry standards.

— Statement of Compliance

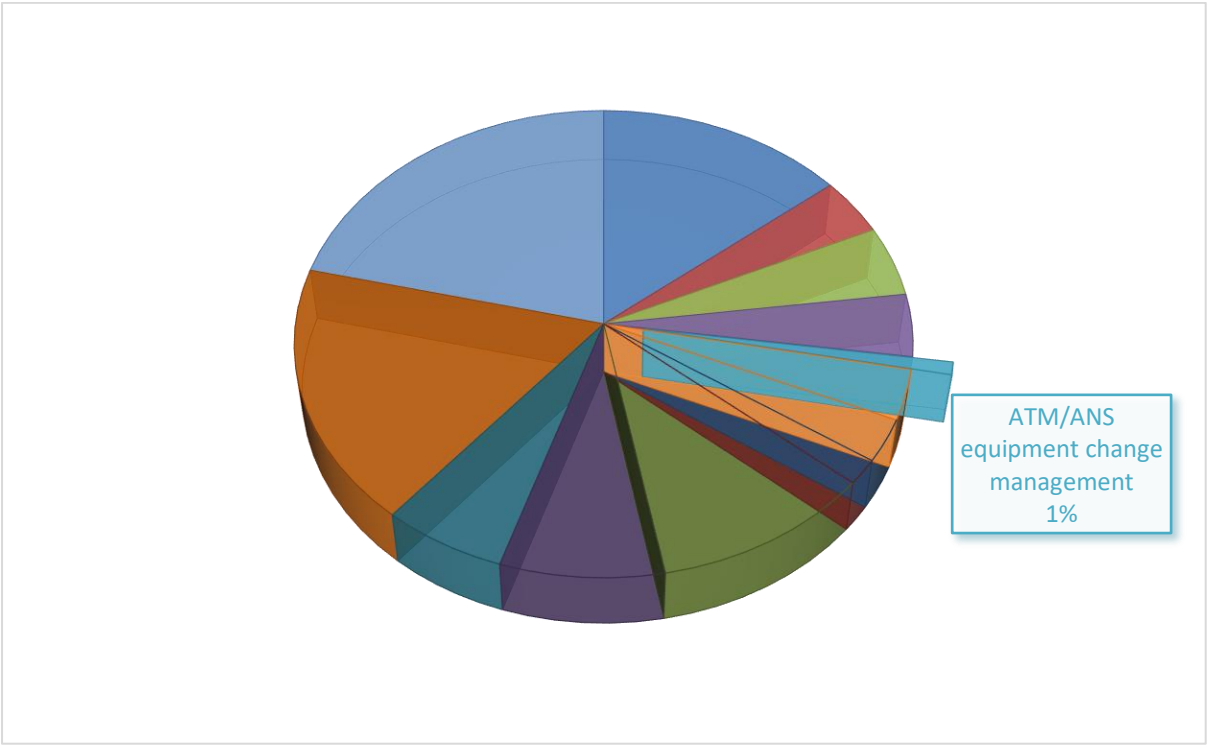
  There is a clear operational need to facilitate the SoC process by providing common specifications. Based on the NPA proposal, it is evident also from the legal point of view that issuing the SoCs would need to be supported by technical specifications. Therefore, EASA has committed to providing also SoC specifications as necessary, in the form of listing the applicable industry standards.

2.5. ATM/ANS equipment change management

Description of the issue

The basic principle in the proposed regulatory solution consulted via NPA 2022-09 is that each change made to ATM/ANS equipment shall be managed by the DPO following an approved procedure defining the classification of the changes and describing how such changes will be managed and notified to EASA. This is included in the implementing act on the approval of the organisations involved in the design and/or production of ATM/ANS equipment (see DPO.OR.B.005(b)).

A relevant number of comments received address the process and responsibilities for the management of changes to the equipment. The main elements raised by the feedback received address the following aspects: whether all changes to the equipment are to be managed by the DPO or some can be managed by the ATM/ANS provider; which types of changes require the re-certification or reissuance of the declarations; how will changes be categorised; how will the ATM/ANS provider be informed about the changes to the equipment and potential impact on its operation.



Considerations and way forward

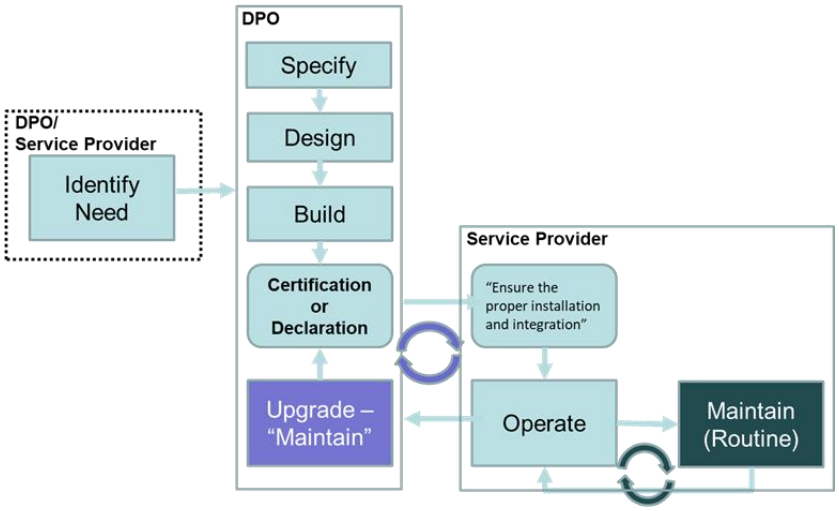
EASA has assessed the feedback provided arriving to the conclusion that no conceptual adaptation was needed at the level of the proposed delegated regulation. Many of the questions and requests for clarification point to the AMC/GM to the implementing act provision DPO.OR.B.005. Considering all the feedback provided, a slight rewording of the mentioned provision DPO.OR.B.005(b) is included in the Opinion to promote clarity.

In this section, a set of considerations are included, intended to provide additional explanation to the allocation of responsibilities and answering the main elements in the questions received:

— All changes to certified and declared equipment are to be done in a controlled manner, being the DPO which received the certificate or issued the declaration for the equipment, the

organisation responsible to ensure continuous compliance of the equipment with the relevant detailed specifications.

The DPO will be required to have in place a procedure for the management of changes to the equipment. This procedure will include the categorisation of changes and establish how the different changes are to be managed and notified to EASA. This procedure will need to be approved by EASA in accordance with provision DPO.OR.B.005.



It is important to differentiate this responsibility of the DPO to manage the evolution of the system from the execution of actions upon a certified system. It is recognised that ATM/ANS providers perform in most cases the routine maintenance, both preventive and corrective, following the instructions prescribed by the DPO. This can typically include testing, calibration, replacement of some constituents as specified in DPO instructions, installation of software patches in accordance with DPO instructions, and implementation of corrective software releases as instructed by DPO. As well, ATM/ANS providers will have the capability to configure the equipment in accordance with the manuals and instructions provided by the DPO.

— Regarding which types of changes would require a re-certification or reissuance of the declaration by the DPO, it needs to be highlighted that this would only be the case for those changes that impact the compliance demonstration with the certification basis, in the case of certified equipment, or the compliance demonstration for declared equipment.

  As an illustration, routine maintenance, both preventive and corrective, is normally performed within the boundaries of the certification or declaration compliance demonstration, and in most cases does not represent an equipment change that would need to be managed by the DPO.

  Upgrades to equipment are normally associated with a change to the functional specifications and require that the DPO manage these changes in accordance with the approved procedure. A need for re-certification or reissuance of the declaration would be present only in cases where the updated functional specifications would impact the compliance demonstration.

— The proposed regulation leaves the categorisation of the changes to be established by each DPO in its change management procedure. This procedure will need to be approved by EASA. In the

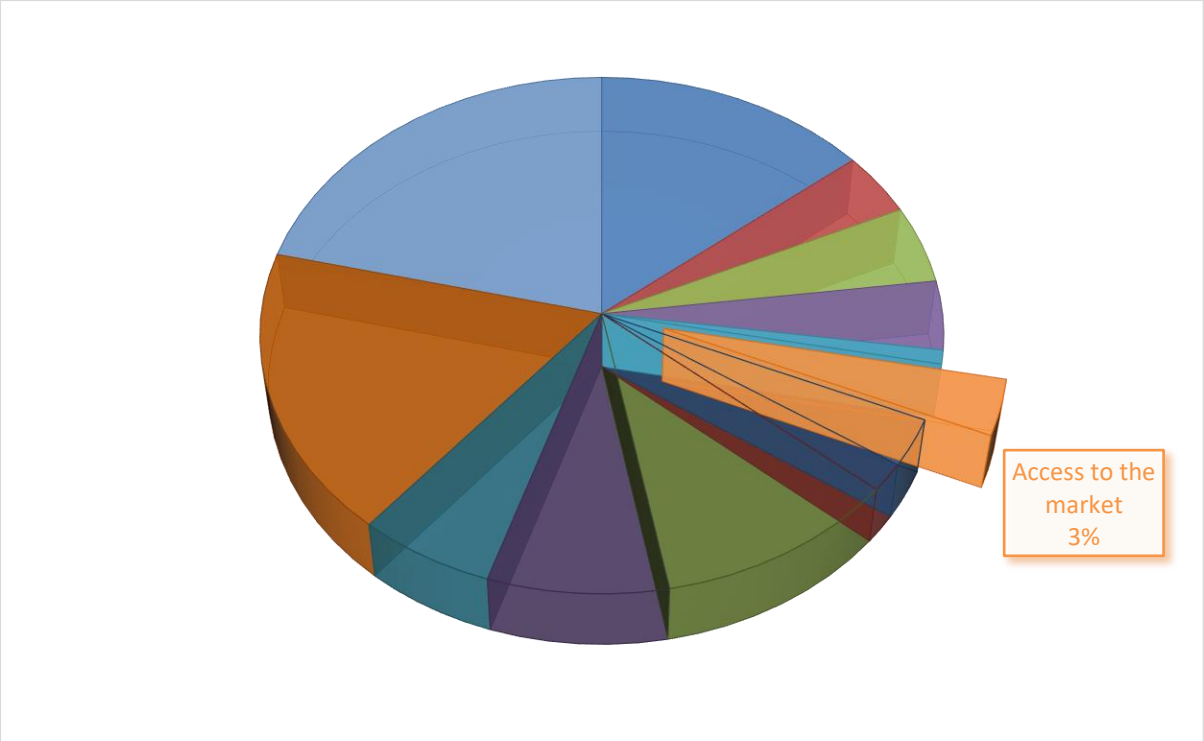
frame of Subtask 3 of RMT.0161, AMC and GM on the categorisation of changes to the equipment will be developed.

— Answering some of the questions, it needs to be highlighted that the transfer of equipment into operations, including operational validations, is part of the activities of the ATM/ANS provider.

2.6. Access to the market

Description of the issue

Various NPA comments provided for a concern that the proposed cConformity Assessment concept may give rise to unnecessary burden to market access, in particular in the case of small undertakings, innovators or niche manufacturing services (e.g. in the case of ANSPs).



EASA fully concurs that any negative effect concerning market access dynamics must be avoided, this principle being also one of the cornerstones of the European aviation market. This is clearly demonstrated by the EASA Basic Regulation (EU) 2018/1139 which defines as EASA's overall objectives (inter alia) the free movement of goods, internal aviation market and competitiveness of the Union's aviation industry, but also the movement of goods worldwide by establishing appropriate cooperation with other countries and their aviation authorities. In the same vein, promoting the mutual acceptance of certificates, cost-efficiency, and effectiveness in regulatory, certification and oversight processes are essential goals also for NPA 2022-09.

As regards the market access, the NPA 2022-09 proposal is based on the relevant provisions of the Basic Regulation which require that the for the design and production of ATM/ANS equipment (subject to certification/declaration by the DPO) for its use in the EU market compliance with the Basic Regulation and its implementing rules is required. Third-country organisations intending to sell equipment in the EU market will need to comply also with the relevant requirements to ensure both that the essential requirements are met and that a level playing field is achieved.

The proposal is considered as achieving a good balance between the need to ensure the necessary integrity, performance, and reliability of critical ATM/ANS equipment and the flexibility to drive innovation and effective deployment of new technologies/functionalities. In particular, the DPO requirements are commensurate with the privileges to declare the compliance of equipment with the applicable declaration specifications, and consist mainly is the demonstration of the availability of a management system with the relevant processes to perform the design and production activities. It should also be clarified that although the proposed European concept, including the DPO requirements, is inspired by the good practices proven over a few decades also in other aviation manufacturing domains, the NPA has been prepared in a close cooperation with the ATM industry to ensure that the specific nature of the ATM market will be taken into account.

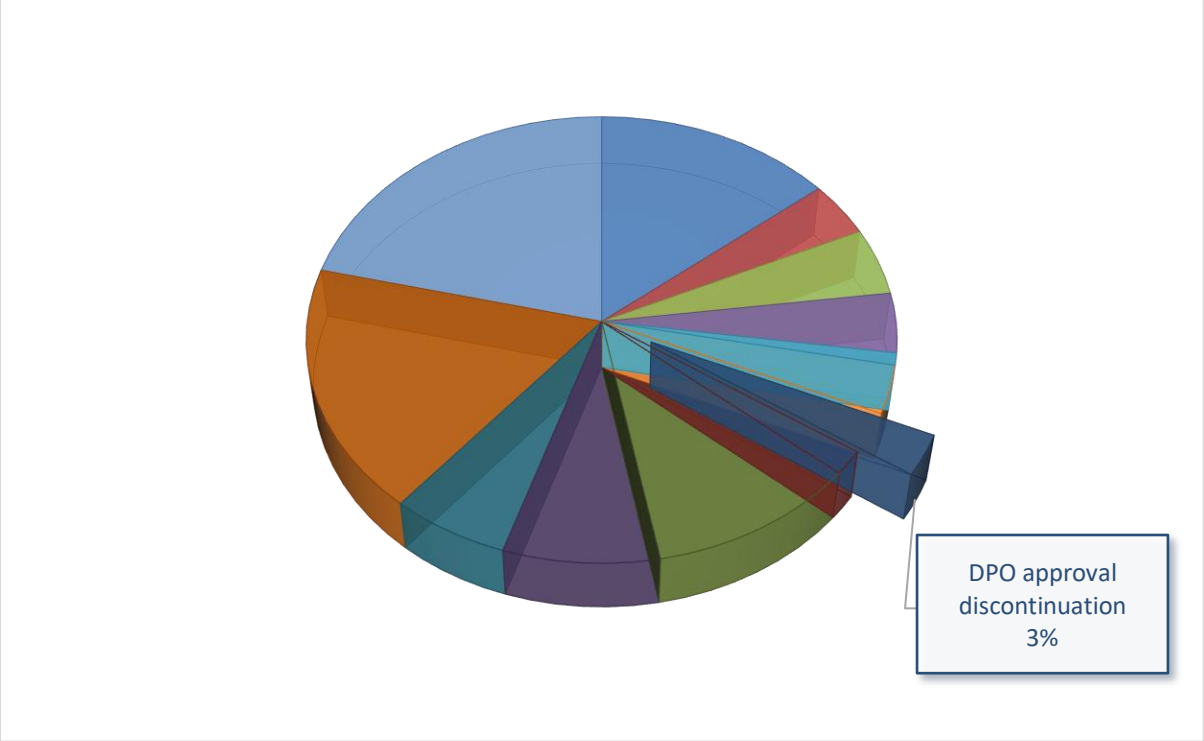
Considerations and way forward

The feedback provided has highlighted the crucial importance of ensuring the level playing field and unhindered market access for all relevant industry sectors. While absolutely concurring with this view, EASA believes that the proposed solution on the level of the regulation provides the needed opportunities for different industry segments and is already commensurate as regards the regulatory requirements. However, EASA fully concurs that the concerns expressed call for further reflection in establishing the necessary detailed specifications and the acceptable means of compliance. It is important to acknowledge that finalising this material will be considered by the respective rulemaking group for RMT.0161 and it will be subject to public consultation.

2.7. DPO approval discontinuation

Description of the issue

Some commenters queried about a situation in which the DPO approval holder has for any reason ceased its operations while its certified or declared ATM equipment is still in operational service. Such situation of the DPO discontinuation may happen also for other reasons; for example, if the DPO approval would be suspended or revoked. This situation could be also initiated by the user (ANSP) in the case of a new equipment maintenance contract.



This situation is not unique to the ATM domain and EASA has concluded that the flexibility provisions in the Basic Regulation are adequate to deal also with this potential situation. Dealing with the situation would be slightly different if the DPO discontinuation takes place due to the end of the transition period, DPO approval suspension or based on ANSPs' unilateral decision. The starting point would be that any unsafe condition can be avoided by ensuring continued occurrence reporting and by close cooperation between EASA as the competent authority and the user (ANSP) with the aim of transferring the DPO responsibilities to another adequate organisation as swiftly as possible. In case of determined unsafe conditions, the equipment certification/declaration would need to be suspended until the DPO responsibilities are assumed by another organisation.

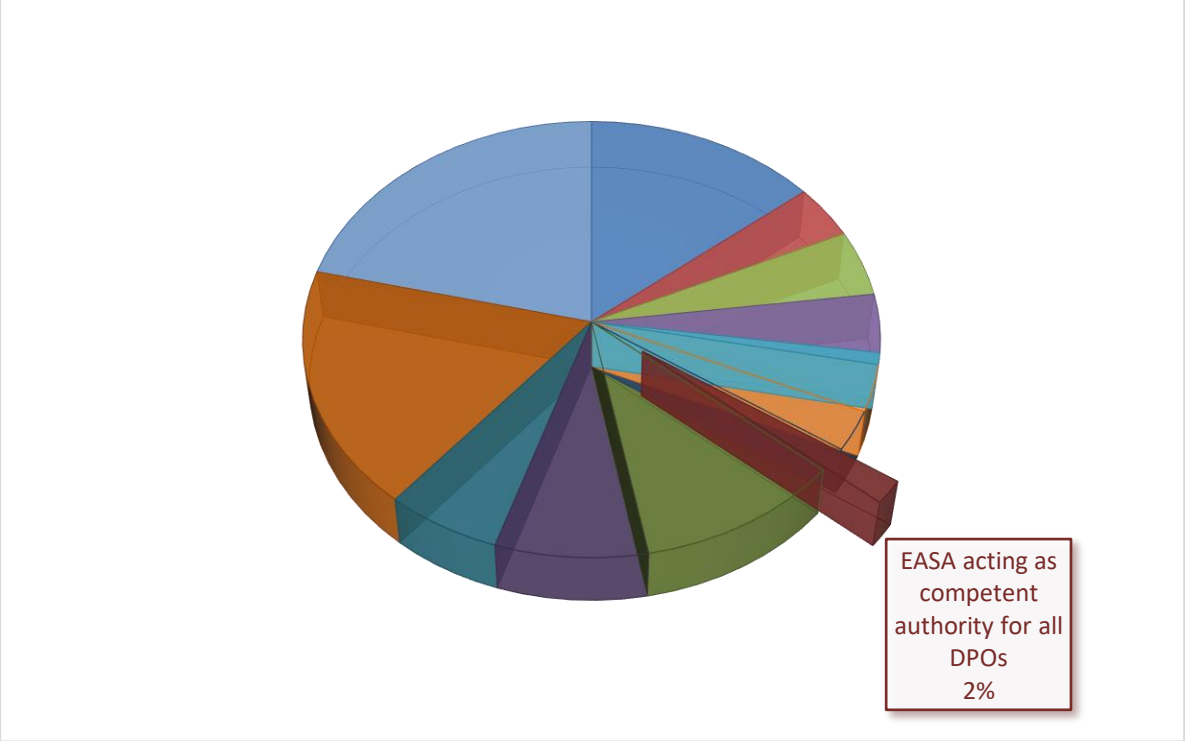
Considerations and way forward

EASA fully agrees that a situation in which the DPO approval is discontinued while the respective ATM equipment remains in operational service is possible, although exceptional by its nature. EASA Basic Regulation contains defined flexibility provisions which provide for the necessary instruments to address the situation without a need to introduce any dedicated mechanism in the respective delegated and implemented acts. At the same time, EASA agrees with the need to provide adequate guidance, and possibly means of compliance, concerning the situation of discontinued DPO approval.

2.8. EASA acting as the competent authority for all DPOs

Description of the issue

Several stakeholders placed questions regarding EASA acting as competent authority for the approval of organisations involved in the design and/or production of ATM/ANS systems and ATM/ANS constituents. These questions concerned the legal basis, pointing to the fact that Article 80(1)(c) of Regulation (EU) 2018/1139 refers to the previous paragraph (b) providing the competency of EASA for approving design and production organisations to systems and constituents for 'pan-European ATM/ANS'.



NPA 2022-09 explained in detail the rationale for the allocation to EASA of the responsibility to act as competent authority for the approval of organisations involved in the design and production of ATM/ANS equipment. The key considerations were:

— Article 80(1)(c) of the Basic Regulation establishes that EASA is responsible for the certification of organisations involved in the design, production, or maintenance of ATM/ANS systems and ATM/ANS constituents, including where they contribute to the Single European Sky ATM Research (SESAR) implementation, used in the provision of the services referred to in Article 80(1)(b), i.e. pan-European ATM/ANS services. However, before the ATM/ANS equipment is designed or produced, it is not possible to determine upfront how it will be used afterwards when it is to be put into service by an ATM/ANS provider, i.e. whether it will be used solely for the provision of ATM/ANS services within the national airspace of a Member State, or also to support service provision in the airspace of other Member States. The future regulatory system should facilitate market access and allow for any ATM/ANS equipment designed or produced in the EU to be potentially used in other Member States and also for the provision of pan-European ATM/ANS services.

— Furthermore, in accordance with Article 80(2) of the Basic Regulation, EASA is responsible for all competent authority tasks related to certificates and declarations for ATM/ANS systems and ATM/ANS constituents (i.e. ATM/ANS equipment), including oversight and enforcement. These functions could only be exercised properly without creating unnecessary complications and administrative burden, when the competent authority for the approval of the organisations involved in the design and production of the equipment is the same authority overseeing the certificates and declarations for such equipment, as this evidence is managed by the above-mentioned organisations.

During the preparation of the Opinion and based on the comments on the NPA mentioned above, EASA has performed further legal assessment on the matter. This assessment has confirmed the

previous conclusions, further stressing that point (c) of Article 80(1) of the Basic Regulation is to be read together with Article 80(2) and the regulatory solution proposed for the certification and declaration of ATM/ANS systems and ATM/ANS constituents, developed following Articles 45 and 47.

EASA considers that the approach in the proposal, allocating consistently the responsibilities related to the certification and receipt of declarations for ATM/ANS equipment and those related to the approval of the organisations involved in the design and production of such equipment, is well balanced and aligned with the principles in the Basic Regulation. Moreover, if the consistency in the allocation of those responsibilities would not be present, that would mean significant complications to the oversight processes and unnecessary administrative burden and cost.

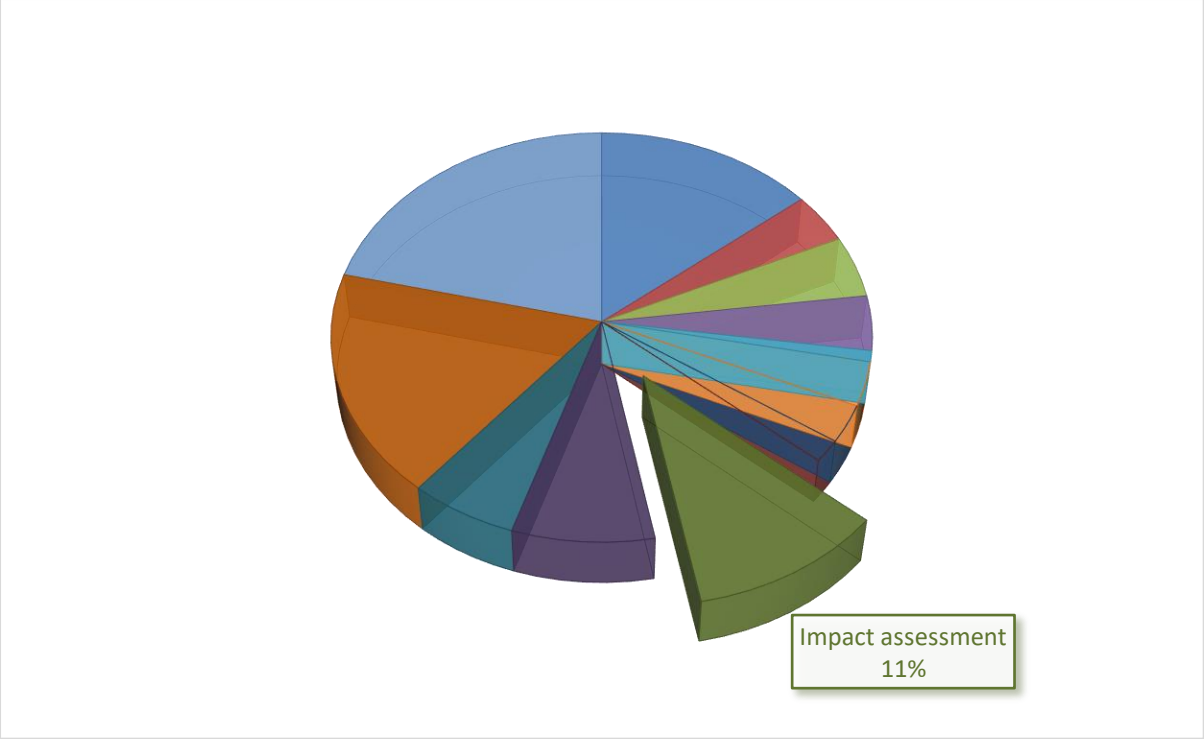
It needs to be stressed that most of the ATM/ANS equipment (in the certification and declaration categories) is actually being designed to be placed on the EU market, as defined in Article 2(4) of Regulation (EU) 2017/373. Those ATM/ANS systems and ATM/ANS constituents cannot be categorised for pan-European or local use a priori, even less is it possible to categorise the organisations involved in the design and production based on their future catalogue of products. The reality is that all systems and constituents would be placed on the EU market and potentially support pan-European services.

The ATM/ANS interoperability established already by the repealed Regulation (EC) No 552/2004, always targeted the pan-European ATM, labelled as the EATMN. Additionally, the SES Interoperability Regulation always aimed at opening the European market for goods in the ATM sector, and pan-European ATM/ANS in that context has always aimed to refer to ATM/ANS systems and constituents that require a specific interoperability approach at European level so they can be used in the entire EU market.

In conclusion, EASA has not identified the need to introduce changes to the proposed regulatory approach.

2.9. Impact assessment, including the following subtopics:

NPA 2022-09 provided details of the issue and the need to address conformity assessment of certain ATM/ANS equipment, especially by means of certifications and declarations. Indeed, the issue is not driven by the safety events occurred in the European system, but mostly by concerns about the efficiency of the previous framework due to a fragmented approach to the conformity assessement of the ATM/ANS equipment and the lack of effectiveness to facilitate the rapid introduction of new technologies through an efficient ATM/ANS market. Furthermore, there is also a risk associated with the lack of an EU framework for the attestation of ATM/ANS equipment, which would delay the introduction of the digital technologies and automation, with a negative safety impact.



Several stakeholders expressed questions regarding the impact assessment of the proposal, which could be grouped in the following 5 sub-topics.

2.9.1 Methodology used and scoring proposed

Description of the issue

When there is not a common unit to measure the impacts, the multi-criteria analysis methodology allows to compare all the options by scoring them against a set of criteria. As it is the case in NPA 2022-09, this methodology proved to be the best option for this assessment in comparison with other methodologies like cost-benefit analysis or cost-efficiency analysis.

The scoring system is explained in the methodology section of the impact assessment (please refer to Section 4.4.1 of NPA 2022-09). Among the elements explaining the scores for each option, it should be considered that:

— the values of Option 0 are defined neutral. Indeed, even if the assessment might show negative or positive elements for Option 0 (baseline scenario), the scores for Option 0 are set equal to 0 to allow a straightforward comparability across the options compared to the baseline scenario;

— the improvements, and therefore the positive scores, of Option 1 from safety, economic and proportionality perspetive compared to Option 0 are explained throughout Section 4.5 ('What are the impacts') in the NPA.

2.9.2 Level playing field and benefits

Comments on whether the proposed measures support level playing field for the European industry

Several commentators questioned the benefits of the proposed NPA highlighting the risk of losing fair competition and increase of monopolies, including the potential additional costs for some companies.

However, the experience gained during the implementation of the SES IOP framework showed the lack of harmonisation in terms of variety of arrangements between NCAs, ANSPs and DPOs across

Europe leading to the lack of level playing field. It is confirmed that the situation remains unsatisfactory as regards similar operations with lower level of integration between national ATM systems and the slow pace in the introduction of new concepts of operations and technologies. The predominance of national technical specifications has led to fragmentation of the ATM/ANS equipment market.

This proposal aims to address these inefficiencies. Indeed, the proposal mitigates the negative impacts of the current framework with different arrangements between the regulated entities (NCAs, ANSPs, and manufacturers) across Europe, with the introduction of harmonised arrangements between NCAs, ANSPs and DPOs across Europe. These arrangements would foster the level playing field in ATM across Europe.

Therefore, all players in an ATM segment of the aviation market would benefit from the same set of rules, thereby promoting innovation, supporting fair competition, and ensuring free movement of persons and services. This is particularly important for technological or business advancements where common 'rules of the game' need to be defined for all actors.

2.9.3 Option chosen

Comments expressing concern on the selected option, questions on the envisaged mechanism (certification)

The preferred option is Option 1 ('Introduction of the ATM/ANS equipment attestation scheme'). The other analysed option (Option 0) is not considered a viable solution in the medium/long term since after 12 September 2023, if no action is taken, the requirements for the issue of EC declarations would cease to apply, and stakeholders would need to continue with the limited set of instructions and guidance developed and issued by their NCAs to ensure that ATM/ANS systems and ATM/ANS constituents are interoperable and operationally suitable in a more and more complex and integrated ATM/ANS environment.

2.9.4 Proportionality

Comments expressing concerns that the proposed regulation will put some manufacturers at a disadvantage, limiting access to the market

It is important to note that not all manufacturers would be affected by this proposal. Indeed, only certain ATM/ANS equipment will be subject to certification/declaration. Manufacturers of equipment subject to the statement of compliance will not need to be approved. The framework provides enough instruments and flexibility to address the different users' needs.

In addition, the proposal offers the possibility for ATM/ANS equipment manufacturers to simplify and at the same time upgrade their processes for complex equipment to attract more customers benefiting from the EASA certification and approvals. ATM/ANS providers would also be likely to benefit from the availability of certified/declared products.

The Agency does not expect any significant impact on smaller DPOs since such DPOs generally produce equipment that would not be subject to certification.

2.9.5 Costs and impact on the market

Comments expressing concern on the economic impact of the proposal and its impact on the EU market

The Agency acknowledges the initial costs linked to the approval of the DPOs. However, it underlines that overall, by harmonising processes and fundamentally reducing overlaps and administrative inneficiencies, costs will be lower in the medium term, and additional benefits will be present in the long term with the development of an EU market and associated improvements. This is valid at an overall system level, but also individually for ATM/ANS equipment manufacturers and ATM/ANS providers.

This proposal would also bring positive benefits for the competent authorities. The establishment of common rules for ATM/ANS equipment within the EU facilitates the efficient use of related resources at Union and national level. Indeed, national authorities will experience less burden and work reduction as all activities linked to the conformity assessment at national level will benefit from a single, mutually recognised EASA certification or a declaration processes. On EASA's side, it is well acknowledged, that this proposal would require appropriate planning and resourcing. The Agency will carry out an assessment to determine the resources needed for the exercise of its newly assigned tasks under this proposal, and will proceed in accordance with the relevant budgetary processes. The implementation of the proposal will require the Agency to plan in advance the necessary resources for this scope of initial certification and continuing oversight of the organisations involved in the design and/or production of ATM/ANS equipment as well as in the certification and registry of the declarations of ATM/ANS equipment, including their continuous oversight. However, it needs to be noted that this oversight by the Agency will fall under the Fees & Charges scheme and therefore the the financial impact on the Agency will be neutral.

With regard to the market opportunities, it is anticipated that the proposal will support the recognition of equipment by both EU and non-EU markets, as EASA specifications being common for the EU market are expected to become one of the references in a wider international context. In this regard, the proposal will also create positive benefits for those ATM/ANS equipment manufacturers marketing their equipment beyond the EU, which would attain advantages from the certification of their products by EASA.

For further details on the other related comments and responses thereto, please refer to Part 2 of CRD 2022-09.