

Management Board Decision

DECISION N° 01-2022

of 02 May 2022

on the procedure to be applied by EASA for the issuing of opinions, certification specifications and other detailed specifications, acceptable means of compliance and guidance material ('Rulemaking Procedure'), and repealing Management Board Decision No 18-2015

THE MANAGEMENT BOARD OF THE EUROPEAN UNION AVIATION SAFETY AGENCY,

Having regard to Regulation (EU) 2018/1139¹ of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (the 'Basic Regulation'), and in particular Article 115 thereof,

WHEREAS:

- (1) The basis for the adoption of Management Board Decision No 18-2015 of 15 December 2015 was Regulation (EC) No 216/2008, which was repealed by the Basic Regulation.
- (2) Rulemaking tasks are mitigating safety and other risks and are, in accordance with Article 6 of the Basic Regulation, identified in the European Plan for Aviation Safety. The regulation of the European Plan for Aviation Safety was introduced in the Basic Regulation in 2018.

¹ [OJ L 212, 22.8.2018, p. 1](#)

- (3) EASA considers for its rulemaking the *Interinstitutional Agreement of 13 April 2016 on Better Law-Making*² and the *Better Regulation* agenda³ of the European Commission as communicated on 29 April 2021.
- (4) Transparency to the Member States, to other affected and interested parties, to the EASA Advisory Bodies established on the basis of Articles 98(4) and 115(2) of the Basic Regulation, and to the public should be provided on how EASA develops regulatory material.
- (5) EASA assessed the experience gained since the adoption of Management Board Decision No 18-2015 as regards the efficiency and effectiveness of the Rulemaking Procedure.
- (6) The Management Board had tasked EASA to revisit Management Board Decision No 18-2015 based on the proposals presented at the Management Board meetings 2021-01 (WP #08).
- (7) EASA consulted the Advisory Bodies established on the basis of Articles 98(4) and 115(2) of the Basic Regulation on the draft text of this Management Board Decision.

Has decided

Section 1 - Subject matter, scope, and definitions

Article 1

Subject matter and scope

This Decision prescribes the procedures to be followed by EASA for the issuing of opinions, certification specifications and other detailed specifications, acceptable means of compliance, and guidance material, as referred to in Article 76(1) and (3) of the Basic Regulation.

Article 2

Definitions

For the purposes of this Decision, the following definitions shall apply:

² Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making – Interinstitutional Agreement of 13 April 2016 on Better Law-Making, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.123.01.0001.01.ENG&toc=OJ:L:2016:123:TOC

³ COM (2021) 219 final 29.04.2021, Communication from the Commission to the European Parliament, the Council, the European and Social Committee and the Committee of the Regions – Better Regulation: Joining forces to make better laws, available at https://ec.europa.eu/info/sites/default/files/better_regulation_joining_forces_to_make_better_laws_en_0.pdf

- ‘Opinions’ are the documents that EASA submits to the European Commission which contain the proposals for amendments to the Basic Regulation and to the delegated and implementing acts to be adopted on the basis thereof;
- ‘Certification specifications’ (CSs), are non-binding technical standards issued by EASA, which indicate the means to demonstrate compliance with the Basic Regulation and with the delegated and implementing acts adopted on the basis thereof, and which are used by persons and organisations for the purpose of certification;
- ‘Detailed specifications’ (DSs) are non-binding standards issued by EASA for the purpose of implementing the Basic Regulation and the delegated and implementing acts adopted on the basis thereof;
- ‘Acceptable means of compliance’ (AMC) are non-binding standards issued by EASA which are used by persons and organisations to show compliance with the Basic Regulation and with the delegated and implementing acts adopted on the basis thereof, or with the CSs and DSs;
- ‘Guidance material’ (GM) is non-binding material issued by EASA, which helps to illustrate the meaning of delegated or implementing acts or CSs and DSs, and which is used to support the interpretation of the Basic Regulation, of the delegated and implementing acts adopted on the basis thereof, and of CSs and DSs;
- ‘Rulemaking’ means the action and process for the development of regulatory material;
- ‘Regulatory material’ means either of the following: proposals from EASA to the European Commission for amendments to the Basic Regulation and to the delegated and implementing acts to be adopted on the basis thereof, certification specifications or other detailed specifications, acceptable means of compliance, or guidance material;
- ‘European Plan for Aviation Safety’ (EPAS) is a plan developed, adopted, published, and subsequently updated at least on a yearly basis by EASA as required by Article 6 of the Basic Regulation, which identifies the main safety and other risks affecting the European aviation safety system and sets out the necessary actions to mitigate those risks;
- ‘Affected party’ means any person or organisation that is or will become subject to the regulatory material developed under this Decision;
- ‘Interested party’ means any person or organisation that is not an affected party and that has a legitimate interest in the regulatory material developed under this Decision;
- ‘EASA Advisory Bodies’ are the advisory bodies established on the basis of Articles 98(4) and 115(2) of the Basic Regulation;
- ‘Impact Assessment’ is a process for gathering and analysing evidence to support decision-making and that contributes to better regulation, ensuring that the regulatory material delivers its full benefits with minimum drawbacks.

Section 2 - Development of regulatory material

Article 3

Initiation of rulemaking action

1. The Executive Director shall initiate rulemaking action by launching a rulemaking task for the development of regulatory material, in accordance with the latest update of EPAS. The Executive Director may also launch a rulemaking task that is not included in EPAS; in this case, the Executive Director shall consult the European Commission and the EASA Advisory Bodies before initiating the action, and include that action in the next EPAS update.
2. The Executive Director shall inform the European Commission, the Member States, other affected and interested parties, the EASA Advisory Bodies, experts, and the public when a rulemaking action has been initiated. The information on the initiation of a rulemaking action shall include a description of the objectives intended to be achieved by the rulemaking action, of the affected parties, and of the working methods intended to be used to develop the regulatory material. This information shall reflect the conclusions of the impact assessment(s) conducted to support the inclusion of the rulemaking action in EPAS, as well as the description of the rulemaking action in EPAS.

Article 4

Development of regulatory material

1. The Executive Director shall ensure that regulatory material is developed based on evidence and sound analysis, and:
 - a. considering all of the following
 - the safety or other risks described in EPAS;
 - the assessment of those safety or other risks, in particular any impact assessment that is conducted by EASA to support the inclusion of the rulemaking action in EPAS; and
 - other information related to the safety or other risks intended to be addressed by the rulemaking task, which was prepared by EASA and shared with the Member States, other affected and interested parties, the EASA Advisory Bodies, experts, or the public before the development of EPAS;
 - b. in accordance with the description of the objectives of the rulemaking task in EPAS and with any other information provided in EPAS or communicated under Article 3(2);
 - c. in line with European Union law, and in particular with the objectives, scope, and principles for measures in Articles 1, 2, and 4 of the Basic Regulation;
 - d. considering the *Better Regulation* agenda of the European Commission;



- e. taking due account of the *Standards and Recommended Practices* included in the Annexes to the *Convention on International Civil Aviation* (Chicago Convention) and of the *Procedures for Air Navigation Services* developed by the International Civil Aviation Organization; and
 - f. considering any other relevant information, in particular relevant policies of the European Commission and reviews or reports issued by EASA.
2. The Executive Director shall ensure that the regulatory material developed is supported by all of the following:
- a. a description of the objectives intended to be achieved by the rulemaking task;
 - b. a rationale to explain how the regulatory material is intended to achieve these objectives, including impact assessments conducted in accordance with Article 5;
 - c. where relevant, a description whether and how the regulatory material
 - transposes *Standards and Recommended Practices* included in the Annexes to the Chicago Convention, or *Procedures for Air Navigation Services* developed by the International Civil Aviation Organization;
 - implements international agreements on the recognition of certificates, which are concluded between the European Union and a third country;
 - d. when deemed necessary, proposed actions to support the implementation of the regulatory material; and
 - e. a description of the arrangements to monitor and evaluate whether and to what extent the objectives of the rulemaking task are being achieved, or a rationale to explain why no such arrangements are provided.

The supporting material shall be proportionate to the criticality of the issue and to the expected impact of the regulatory material.

Article 5

Impact assessment

1. The Executive Director shall conduct impact assessments to support decision-making, when developing the regulatory material in accordance with Article 4.
2. In case EASA conducted impact assessments to support the inclusion of the rulemaking action in EPAS, the Executive Director shall ensure that these assessments are updated, when necessary, and that where other regulatory options are identified when developing the regulatory material, these impact assessments are complemented with a new assessment.



3. The Executive Director shall ensure that the contributions from the EASA Advisory Bodies received in accordance with Article 3 ('Functions') of Management Board Decision No 19-2015 and Article 3 of Management Board Decision No 20-2015 are duly considered when developing an impact assessment.
4. The impact assessment shall be proportionate to the criticality of the issue and to the expected impacts of the regulatory material.
 - a. When the impacts have been assessed in other processes, the Executive Director may determine to refer to or complement those assessments, while ensuring that the objective set out in paragraph 1 is achieved.
 - b. When the impacts cannot be clearly identified beforehand, or the expected impacts are negligible, or other considerations outweigh the need for conducting a detailed impact assessment, the Executive Director shall, as a minimum, ensure that the existence of an issue and its underlying causes are verified and that a general assessment of the benefits and drawbacks of the regulatory material supports the need for rulemaking action.

When the determination to apply point a. or point b. is not already described in the working methods communicated in accordance with Article 3(2), the Executive Director shall consult the EASA Advisory Bodies on the intent to do so. In case the Executive Director determines, in consideration of the feedback received from the EASA Advisory Bodies, to apply either of these points, the Executive Director shall ensure that the description of the working methods communicated in accordance with Article 3(2) is updated.

Article 6

Engagement and consultation

1. The Executive Director shall allow for the widest possible participation of the Member States, other affected and interested parties, the EASA Advisory Bodies, experts, and the public during rulemaking by engaging them during the development of the regulatory material, and/or by consulting them in that process.

Where required by Article 115(2) of the Basic Regulation, the Executive Director shall also allow for the participation of the European Defence Agency and any other competent military experts designated by the Member States, the Union social partners and other relevant stakeholders.

2. The Executive Director may reduce the participation described in paragraph 1 in either of the following cases:
 - a. when there are justified reasons to expect that such participation will not lead to new actionable insight;



- b. when there are legal obligations that outweigh the need for participation or make it obsolete;
- c. in other cases when the EASA Advisory Bodies have agreed to it.

When the reduction of the participation in accordance with point a. or point b. is not already described in the working methods communicated in accordance with Article 3(2), the Executive Director shall consult the EASA Advisory Bodies on the intent to do so, and consider the feedback received from them before determining to reduce participation. The Executive Director shall ensure that the description of the working methods communicated in accordance with Article 3(2) is updated.

- 3. The Executive Director shall determine, based on the impact assessment(s) conducted to support the inclusion of the rulemaking action in EPAS, considering the expected impact of the regulatory material, all of the following:
 - a. the most suitable timing to engage and/or consult;
 - b. the most suitable means and tools to achieve the widest possible participation; and
 - c. the length of the periods of this participation, which should be appropriate so as to enable the provision of meaningful comments.

When the means of participation in accordance with this paragraph are not already described in the working methods communicated in accordance with Article 3(2), the Executive Director shall update accordingly the description of the working methods as laid down in Article 3(2).

- 4. When consulting the Member States, other affected and interested parties, the EASA Advisory Bodies, experts, or the public during the development of the regulatory material, the Executive Director shall ensure that the draft supporting material developed in accordance with Article 4(2) is accessible to the consultees.
- 5. The Executive Director shall ensure that those engaged in the development of regulatory material, or those consulted on it, are informed that their comments, or a summary of them, will be made public, and shall be treated in accordance with the rules on access to documents.
- 6. When regulatory material is developed with the support of affected or interested parties, or external experts, the Executive Director shall:
 - a. ensure that they have declared their interests before in any form and manner engaging in, or contributing to, rulemaking; and
 - b. make transparent that EASA engages affected or interested parties, or experts in the development of the regulatory material, and provide information on their qualification and expertise.

7. The Executive Director shall ensure that comments, concerns, suggestions, and any other feedback received during engagement and consultation is reviewed and duly considered when developing the final regulatory material.
8. The Executive Director shall ensure, in accordance with Article 115(1)(c) of the Basic Regulation, that feedback is provided to commenters and to the public on who was engaged and/or provided comments during the consultation of the draft regulatory material, which comments were received, how such engagement and/or consultation was used in rulemaking, and how the contributions received were considered.
9. Without prejudice to the obligation to allow for participation of the EASA Advisory Bodies in accordance with paragraph 1, before issuing any draft opinion proposing to the European Commission amendments to the Basic Regulation and to the delegated and implementing acts to be adopted on the basis thereof, the Executive Director shall seek the advice of the advisory body established on the basis of Article 115(2) of the Basic Regulation whether there are any substantially divergent views of Member States.

Section 3 - Issuance and publication of regulatory material

Article 7

Issuance

1. The Executive Director shall issue EASA's proposals to the European Commission for amendments to the Basic Regulation and to the delegated and implementing acts to be adopted on the basis thereof in the form of opinions. When doing so, the Executive Director shall provide the European Commission with an assessment as to whether the proposed act at stake is of specific relevance to citizens, and it is therefore justified, proportionate, and reasonable to have the act translated and consulted in more than one language.
2. The Executive Director shall adopt and issue CSs and other DSs, AMC, and GM in the form of ED decisions.

Article 8

Publication

The Executive Director shall ensure:

1. that opinions issued in accordance with Article 7(1) and regulatory material issued in accordance with Article 7(2) are published in the Official Publication of EASA; and



2. access to the supporting material established in accordance with Article 4(2) and to the feedback provided to commenters and to the public in accordance with Article 6(8).

Section 4 - Final provisions

Article 9

Retention of documents

1. The Executive Director shall ensure that the documentation of rulemaking is retained in accordance with the document and record management policy of EASA and the applicable EU law so as to enable EASA to provide justification for its decisions and to show that the appropriate procedures were followed.
2. The Executive Director shall ensure that the regulatory material issued is retained for an indefinite period.

Article 10

Repeal

Management Board Decision No 18-2015 is hereby repealed.

Article 11

Entry into force

This Decision shall enter into force on the day of its publication in the Official Publication of EASA.

Done in Warsaw, 04 May 2022

(signed)

PIOTR SAMSON
Chair of the Management Board

