

Note: This is not an official version of the MB Decision. The information provided in this document is provided for information to support the application of this Decision. It provides the 'rationale' for several provisions of the Decision, with the objective to show how they are intended to be applied.

# Management Board Decision

Decision No **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 AVIATION SAFETY AGENCY,

Having regard to Regulation (EU) 2018/1139<sup>1</sup> 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for the adoption of Management Board Decision No 18-2015 of 15 December 2015 was Regulation (EC) No 216/2008, which was repealed by the Basic Regulation.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.

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<sup>1</sup> [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*<sup>2</sup> and the *Better Regulation* agenda<sup>3</sup> 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:

#### RATIONALE

Terms are rearranged in order of appearance in the text.

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<sup>2</sup> 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](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)

<sup>3</sup> 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](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;

#### RATIONALE

DS are newly introduced in the new Basic Regulation.

- ‘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;

#### RATIONALE

‘Rulemaking’ is an action type identified in the EPAS which is found suitable to mitigate a safety or other risk, if necessary after conducting an assessment of those risks and after an assessment of the best intervention strategy (BIS). Accordingly, the BIS and the EPAS are not part of ‘rulemaking’, but preceding it. The BIS and EPAS are part of the process to identify suitable mitigation actions and plan them. This process can lead to a variety of possible mitigation actions, one of which is rulemaking (others are safety promotion, research etc.).

In this MB Decision, ‘rulemaking’ is used to describe both, the action itself, as well as the process for the overall development of a regulatory proposal starting with the initiation of a rulemaking action (Art. 3) until the publication of the opinion or decision (Art. 8).

On the term ‘regulatory material’, see definition below.

- ‘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;

#### RATIONALE

‘Regulatory material’ is a new terminology. Purpose: to describe all types of ‘rules’ which are issued by the Agency, either in the form of opinions or decisions of the Executive Director of the Agency. Previous versions of the MBD focused on the term ‘rules’, which is not precise and led to confusion, or on the term ‘rulemaking deliverables’, which can be any deliverable of the rulemaking process, incl.

ToRs or NPAs. 'Regulatory material' is to be understood in a broader sense, since e.g., guidance material of course do not 'regulate' anything.

- '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;

#### RATIONALE

The obligation in Art. 6 of the Basic Regulation to develop and update annually an EPAS is one of the main changes to that Regulation that was not reflected in the MB Decision from 2015. The draft MBD as presented here ensures that the rulemaking process builds upon what has been assessed, consulted, agreed and published in EPAS. It also ensures that steps which are conducted for the development of EPAS are not repeated in the rulemaking process.

- '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.

#### RATIONALE

With reference to the description of impact assessment in the Better Regulation agenda of the European Commission an impact assessment supports decision making by verifying the existence of an issue/problem, identifying its underlying causes, assessing whether action is needed, and analysing the advantages and disadvantages of available solutions (based on specific assessment criteria: safety, environment, social, economic and general aviation and proportionality issues).

Considering the uncertainties and unclarity with the objectives of conducting impact assessments and the improvements related to it introduced in EASA processes in the past years, and considering that only parts of the necessary impact assessment(s) supporting and justifying the regulatory material are conducted within the core rulemaking process (i.e., when the regulatory material is developed) itself, a new definition is suggested (replacing the existing definitions of PIA and RIA). This new definition is kept general, reflecting the essence of what impact assessment is about.

#### SUPPORTING EXPLANATION: IMPACT ASSESSMENT

The objectives of impact assessments and the different sort of impact assessments necessary to support rulemaking are not always fully understood. Therefore, this supporting explanation is provided.

In the context of its Better Regulation agenda the European Commission describes 'impact assessment' as follows (wording slightly adapted): *Impact assessment verifies the existence of an*

*issue/problem, identifies its underlying causes, assesses whether action is needed, and analyses the advantages and disadvantages of available solutions. Impact assessment promotes more informed decision-making and contributes to better regulation which delivers the full benefits at minimum cost. However, impact assessment is only an aid to decision-making and not a substitute for it.*

In this spirit, impact assessment(s) in the context of (EASA) rulemaking ensure(s) that the final regulatory material is based on one or several assessments

- demonstrating that
  - the intervention by rulemaking was necessary and justified as the best intervention to address an issue (in the practice of the Agency: a BIS);
  - the positive effects of regulating the issue outweigh its negative impacts (in the practice of the Agency: a Regulatory Impact Assessment); and
  - the regulatory material developed is the simplest, least costly way to regulate the issue without creating unnecessary red tape to achieve the greatest possible benefits (in the practice of the Agency: an additional element of the Regulatory Impact Assessment);
- or supporting decision-making at any stage in the process towards the final regulatory material.

Whenever there is an important decision or direction to take to get to the final regulatory material, this decision should be taken in consideration of an impact assessment. It is an iterative assessment, where one assessment builds upon the previous ones. In the end, the impact assessment provides information that demonstrates that rulemaking was necessary (the most appropriate way to mitigate a safety or other risk identified), that the positive effects of the regulatory material outweigh its negative effects, and that the regulatory material is the simplest, least costly way to regulate the issue without creating unnecessary red tape to achieve the greatest possible benefits.

*Note: In this sense, where the term ‘impact assessment’ is used without any additional qualifier, the intent is to refer to the complete set of impact assessment(s) that support the final regulatory material – irrespective whether the impact assessment(s) was conducted during the development of the regulatory material under this procedure, or during the planning and programming process (leading to the BIS and EPAS) and outside of this procedure and preceding rulemaking.*

While all these assessments can be conducted in parallel to or at the end of the development of the regulatory material, the Agency applies in practice (since a couple of years already) a gradual approach to conduct these assessments. This practice also reflects the new Article 6 of the Basic Regulation on EPAS and supports the implementation of it: Rulemaking is only one possible action to mitigate safety or other risks for the European aviation safety system; as a consequence, at least the first assessment typically precedes any planning of a rulemaking action in EPAS.

*Note: In this sense, when the intent is to refer to the BIS and other impact assessments developed in order to decide whether rulemaking is a suitable action to address an issue, this MBD uses the term ‘impact assessment(s) conducted to support the inclusion of the rulemaking action in EPAS’.*

Consequently, the draft MBD does deliberately not use the terms BIS and or/RIA and there is also no definition of those impact assessments. For the sake of clarity supporting the understanding of the BIS

and RIA as specific sorts of impact assessment in the context of this MBD, the Agency's understanding of these two impact assessments is the following:

- 'Best intervention strategy' (BIS) is an assessment of an issue that presumably deserves the intervention of the Agency with the aim of determining whether intervention is justified, the positive and negative impacts of possible actions, and which actions are the most appropriate to address the issue.
- 'Regulatory impact assessment' (RIA) is a systematic approach to assess the expected positive and negative effects of the regulatory material.

## 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.

#### RATIONALE

In the first sentence there is a new link to EPAS, which provides the initial timeline for an action, including when it is supposed to start. However, the fact that an RMT is not yet programmed shall not prevent its initiation – if it is necessary to mitigate a safety or other risk. This could be the case, for instance, where a rulemaking action is identified, e.g., through a BIS, shortly after the EPAS was last updated. Therefore, the second sentence was introduced. In such a case, EASA shall provide the opportunity to the advisory bodies to provide their views on the description of the rulemaking action, as they would have done had this action been included in the draft EPAS edition when it was consulted. In addition, an obligation is introduced on EASA to include the action in the next edition of EPAS.

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.

#### RATIONALE

Today, there is a long process to develop the ToRs, which in the meantime provides limited value since most of the information provided there has already been discussed, analysed, consulted and communicated before, in particular in the BIS and in the EPAS (all of the information required by

Article 4(2) of MB Decision 18-2015 and most of the other, non-mandatory information provided in the ToR today is already available in the BIS or in EPAS). The BIS and EPAS did not exist when the ToR process was initially developed; and when the MBD was amended last time, the processes to develop these two was ongoing. With this revision of the MBD it is now possible and expedient to skip this process.

That does not mean that no ToR or similar information will be provided any longer. It is necessary to create transparency when a RMT is initiated and to provide a summary of the essential elements of the RMT (like the objectives, affected parties and working methods). This can be done e.g., in the form of a ToR, or other similar format. Therefore, the ToR article has been redrafted to describe the objective (to create transparency). The MBD does not need to describe what the form of the information is.

How is the information provided: the information should be provided in a structured manner in a unique form (e.g., as ToR) proactively to the advisory bodies, and in addition on the website. In order to avoid duplication and contradiction between information presented at several occasion, the information may repeat or refer to information that is available on other accesible data/information sources.

Which information is provided: a) the objective as developed in the impact assessment(s) preceding the inclusion of the RMT in EPAS (in practice for example the BIS) or as described in the summary of the action in EPAS; b) the affected parties; c) the working methods to develop the regulatory proposal: this includes information how the regulatory material is intended to be developed (as an Agency task, with expert groups, ...), whether additional impact assessments are planned, how the draft regulatory material is intended to be consulted, and any other information that is relevant to provide transparency to stakeholders in order to ensure that the advisory bodies can properly advise and all affected and interested parties can provide their view. Article 5(4) and Article 6(2) and (3) provide obligations to update the information when main working methods are decided or changed after the initiation of the rulemaking action.

#### *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;

#### **RATIONALE**

New link to EPAS, where the risks and issues intended to be mitigated with the RMT are described (not only in Vol. II, but also in Vol. I).

- 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

#### **RATIONALE**

In most cases, an impact assessment (often a BIS and related RIA) will already exist when the Agency starts to develop regulatory material; Member States and other affected and interested parties will



have been engaged and/or consulted on it. The conclusions of this / these impact assessment(s) will have been widely communicated. The contents of those assessments provide the framework for the development of the regulatory material. A link is therefore established here.

- 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;

#### RATIONALE

Where the Agency developed and shared with stakeholders pre-rulemaking documents, which shall govern the RMT later, those shall be considered. They create expectations and the RMT is a logical consequence of that information. Examples are concept papers, roadmaps, prototype rules, or draft regulatory material included in a BIS.

- 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);

#### RATIONALE

The 2<sup>nd</sup> part of the sentence ('and any other information ...') is a placeholder for information provided today in the ToR and not reflected in the EPAS issue and objective, or in the BIS. Where the Agency provided such information i.a.w. Article 3 (2), it shall be considered when developing the regulatory material.

- 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;

#### RATIONALE

Art 1 and 4 BR now describe everything that is listed in Article 6(2) of the MBD 18-2015, for example that EASA shall consider technical standards developed by standardisation and other industry bodies to be used as a means of compliance with the Basic Regulation, and with the delegated and implementing acts adopted on the basis thereof, where appropriate.

- d. considering the *Better Regulation* agenda of the European Commission;

#### RATIONALE

MBD 18-2015 does not make a link to the Better Regulation agenda of the Commission. By including this reference now, it is intended to link into three important aspects of 'better regulation' for the development of the regulatory material:

- 1) important decisions need to be supported by impact assessments, in particular the decision
  - whether to initiate rulemaking: demonstrating that rulemaking was necessary (the most appropriate way to mitigate a safety or other risk) and that the positive effects of the regulatory material outweigh its negative effects,
  - how to achieve that the regulatory solution is the simplest, least costly way to regulate the issue without creating unnecessary red tape to achieve the greatest possible benefits;
- 2) the regulatory material itself is fit for purpose: this links into those elements of the better regulation toolbox which are linked to the development of the regulatory material itself, in particular those related to regulatory fitness (REFIT): simpler, more targeted, easier to comply, fit for purpose, fit for future-proof, etc., regulatory material.



3) stakeholders have the possibility to contribute in the development of the regulatory material and the process of the development of the regulatory material is transparent.

- 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.

#### RATIONALE

New point added in order to highlight the need to consider any information, which may be relevant for the rulemaking action.

Examples of reviews or reports issued by the Agency are the Annual Safety Review (Art. 72 (7) BR), the Standardisation Report (Art. 85 BR), the Environmental Report (Art. 87 (4) BR), the Review on interdependencies between civil aviation safety and socioeconomic factors (Art. 89 BR).

- 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

#### RATIONALE

Implementation support may be necessary especially when new or amended Regulations are proposed which will lead to major changes in the EASA system. In these cases, the regulatory material should be complemented with information on actions that are proposed to support the implementation of it.

- 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.

#### RATIONALE

Point (e) has been strengthened in order to reinforce the importance of monitoring the implementation and application of the regulatory material and its ex-post evaluation. Already when developing the regulatory material, the Agency needs to consider whether the criticality of the issue and the expected impact of the regulatory material require monitoring during its implementation whether the intended objectives are being achieved ; and if so, the arrangements how to best do it. Another possibility that shall be considered is whether and when to carry out an ex-post evaluation.

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.

#### **RATIONALE**

With reference to the description of impact assessment in the Better Regulation agenda of the European Commission an impact assessment verifies the existence of an issue/problem, identifies its underlying causes, assesses whether action is needed, and analyses the advantages and disadvantages of available solutions (based on specific assessment criteria: safety, environment, social, economic and general aviation and proportionality issues).

‘Verification of the existence of an issue/problem and its underlying causes’ is always carried out. It is available as part of the introduction of the impact assessment, e.g., of the BIS, and/or the explanatory note of e.g., any notice of proposed amendment today, i.e. the consultation document.

The assessment ‘whether action is needed’ (and which action) is typically already carried out before a rulemaking action is included in EPAS. As a minimum, the Agency always assess the main benefits and drawback. This information – even if carried out before – today is provided as part of the explanatory note of e.g., any notice of proposed amendment today. Where the assessment of the main benefits and drawback does require more detailed assessment it is carried out in form of a BIS to support the decision to include a rulemaking action in EPAS.

The ‘analysis of the advantages and disadvantages of available solutions’ is sometimes, at least in a general manner, also available before the Agency includes a rulemaking action in EPAS, since the Agency will have conducted a RIA as part of the BIS when rulemaking is one possible action (next to other possible options, e.g., safety promotion), or when rulemaking is the only option. If that RIA concluded that the negative impacts of the regulatory material are not commensurate with the expected benefits, no RMT will be programmed in EPAS, hence no RMT will be initiated in accordance with Article 3.

While all of these analyses happen outside of the process of developing the regulatory material (i.e. when updating EPAS), these impact assessments need to be updated (or checked whether they need to be updated) during the process of developing the regulatory material, and – where new regulatory options are identified when developing the regulatory material – complemented as part of the rulemaking task, assessing what is the simplest, least costly way to achieve the objective, without creating unnecessary red tape to achieve the greatest possible benefits.

Only in those cases where no RIA was conducted as part of the BIS while updating EPAS, and no other assessment of the impacts has been conducted by the Agency before planning the rulemaking action in EPAS, an impact assessment will still need to be conducted.

The impact assessment supporting the regulatory material developed in accordance with Article 4 at the end of the rulemaking task is the sum of all impact assessments conducted, which supported decision-making from the initial identification of the issue until the finalisation of the regulatory material addressing the issue. In that sense, impact assessment is an iterative process.

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.

#### RATIONALE

The article was redrafted in order to change the perspective of the obligation and to eliminate a duplication with the same obligation existing in other MB Decisions. Today's MB Decision 18-2015 contains an obligation on the ABs to support impact assessments by providing data. This same obligation is also included in the MB Decisions 19 and 20-2015 on the establishment of the MAB and SAB. What is relevant for the MBD here (i.e. for the procedure how the Agency conducts rulemaking) is that the contributions from the ABs (as provided in accordance with their obligations under MB Decisions 19 and 20-2015) are duly considered when the Agency develops 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.

#### RATIONALE

Proportionality of impact assessment is necessary since impact assessments are no ends in themselves. They support the decision-making process by providing data and information on whether rulemaking is a suitable action and beneficial overall, and on what is the simplest, least costly way to achieve the objective, without creating unnecessary red tape to reach the greatest possible benefits. While all regulatory material requires an impact assessment covering an issue analysis, and an assessment of the main benefits and drawbacks as a minimum, the further level of detail needed depends on the criticality of the issue and the expected impacts. This proportionality is already applied today: for certain proposals the complete (light) impact assessment consists of the issue analysis (e.g., in chapter 2.1. of the explanatory note of an NPA), and the description of the expected benefits and drawbacks (e.g., in chapter 2.4 of the explanatory note of an NPA). For other proposals there is in addition a detailed impact assessment (e.g., in chapter 4 of the explanatory note of an NPA).

- 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.

#### RATIONALE

When relevant impacts have been assessed in other processes there is no need to redo the complete assessment. In such case reference can be made to those assessments. If those assessments need to be complemented, e.g., to add considerations or to adapt information that was used as input to the assessment, this can be done in order to make efficient use of those other assessments. An example

is where the Agency intends to take on board a recommendation from an ARAC group in the U.S., and where this recommendation is based on an impact assessment done as part of the ARAC tasking. The impact assessment becomes by reference, and in case done, together with the complementary assessment, an EASA assessment supporting the EASA decision-making, and is part of the supporting material of the regulatory material developed, including the consultation of it.

- 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.

#### RATIONALE

A description of the issue and an analysis of it, the definition of the objectives, together with an assessment of the main benefits and drawbacks will always be made by EASA and provided as supporting material (see Article 4(2)). This is considered to be the minimum of an impact assessment that is always provided. A more detailed analysis of the impacts (as part of the impact assessment) is not always possible, needed or proportionate.

Since the Agency's practice was for a long time to differentiate between such 'light' and 'full' impact assessments and stakeholders are requesting transparency on when EASA does not do a 'full' impact assessment, paragraph 4(b) provides an interpretation of proportionality where no such 'full' analysis is provided as part of the impact assessment.

Examples for any of those cases where only a 'light' impact assessment may be conducted may be the following:

- 'when the impacts cannot be identified beforehand': this may be the case where e.g., the regulation is an enabler like a framework to develop an activity (e.g., the U-Space) or it is not possible to anticipate new business models or the effect of new technology. Also, where the regulatory material is predominantly meant to enable new technologies or new business models.

- 'when the expected impacts are negligible': not every regulatory material requires an impact assessment. Minimum thresholds are common and in line with Better Regulation principles. Typical, clear examples are where only guidance is provided in the regulatory material; furthermore sometimes the AMC may have no (additional) impact; the impact is created by the requirement in the regulations for which the AMC provides a possible way demonstrating compliance. Also, CSs may in certain cases not create considerable impacts, since (e.g., in initial airworthiness) they provide standards for new design and the design of new products can be developed from the outset with these new standards in mind; and since CSs are not binding and compliance can always be demonstrated differently (CSs are a part of the certification basis, but not the only part). Apart from these cases, there may be other cases where the impacts created are negligible, e.g., where there are minor amendments to Regulations. Where proposed Regulations only alleviate regulatory burden, the Agency may also refrain from conducting a detailed impact assessment.

- 'when other considerations outweigh the need for conducting an impact assessment': an impact assessment is supposed to support the decision-making process by providing data and information on what is the simplest, least costly way to achieve the objective, without creating unnecessary red tape to reach the greatest possible benefits. If there is no choice of the regulator to develop regulatory material in a certain way, a detailed impact assessment is useless. This may be the case for instance where the Agency develops a proposal for the transposition of ICAO SARPs for which it has been

decided previously to transpose those, and where e.g., interoperability with other ICAO States needs to be ensured; or where the EU MSs have decided at EU Council level to transpose (and how) a certain standard (i.e. not to notify a difference to ICAO).

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.

#### RATIONALE

There should be transparency for all cases where only a light impact assessment is conducted, and the advisory bodies should be consulted before determining to use a light impact assessment. In most of the cases this will already have been done in the context of the consultation of the draft EPAS, which contains the information for any planned rulemaking action whether a detailed impact assessment is intended or not. If that was not the case, a dedicated consultation should take place prior to consulting the draft regulatory material; furthermore the working methods of the rulemaking action shall be 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.

#### RATIONALE

This article combines all ways of how stakeholders can participate in rulemaking. Participation can happen through engagement, or through consultation. The term 'engagement' replaces the term 'involvement' used by the current MB Decision in order to better reflect the terminology of the Better Regulation agenda of the European Commission.

'Engagement' of stakeholders in the development of regulatory material or the impact assessment has been combined in this article with 'consultation' of stakeholders on the draft regulatory material, i.e., throughout the rulemaking in order to deal with all stakeholder participation aspects in one article. 'Engagement' and 'consultation' may be mutually dependent aspects of participation: sometimes it is important to engage, sometimes to consult, sometimes both. Sometimes more engagement may lead to less consultation or less engagement may require wider consultation.

Article 115(1)(a) BR requires that the procedure shall draw on the expertise of the civil, and where appropriate, military aviation authorities of the Member States. This is reflected in a twofold way in paragraph 1: experts from both authorities are captured under 'Member States'; in addition, the advisory body established on the basis of the second sentence of Art 115(2) BR, i.e. the MAB, also captures those experts.

Article 115(1)(b) BR requires that the procedure shall, whenever necessary, involve experts from relevant interested parties, or draw on the expertise of the relevant European standardisation organisations or other specialised bodies. This is captured in paragraph 1 by ‘other affected or interested parties’ and the general term ‘experts’.

Article 115(1)(c) BR requires that the Agency widely consults interested parties. This is reflected in paragraph 1.

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.

#### RATIONALE

The last two sentences of Article 115(2) BR require the consultation of EDA and other military experts designated by the Member States, and the Union social partners and other relevant stakeholders under the conditions described in those sentences. The obligation is repeated here to achieve a comprehensive MB Decision. The obligation here goes slightly beyond the obligation in the BR. In the BR it is required to consult; however, the Agency believes that it may also be useful to already engage those stakeholders, if necessary. Therefore, the term ‘participation’ is used.

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.

#### RATIONALE

Paragraph 2, together with the ‘urgency’ now dealt with in paragraph 3(c), is the current Art. 15 ‘direct publication procedure’ in more general terms.

The term ‘may’ is used, so that the Agency can still decide to widely engage and/or consult stakeholders, if considered necessary.

An example of where participation may not lead to actionable insight is where the regulatory material has been widely consulted before EASA starts its rulemaking action. This may have been done through processes in e.g., ICAO, FAA (e.g., ARAC), EASA (e.g., certification policy), or SDOs where MS and other affected and interested parties had the opportunity to comment, knowing that the EASA regulatory material will reflect that previously consulted. If EASA considers that the consultation of its regulatory

material would address the same stakeholders on the same issues and therefore would not result in comments other than those provided before, it may therefore determine to reduce the consultation. In addition, the planning and programming process of the Agency for the development of EPAS can be an example, namely when the draft regulatory material and the regulatory impacts had already been included in the impact assessment(s) conducted to support the inclusion of a RMT in EPAS.

Furthermore, there may be situations where legal obligations conflict with the objective of engaging and consulting stakeholders. This may be the case where the Agency has no possibility to consider the comments received, or even to draft the regulatory material in a different way than proposed (e.g., for the transposition of certain ICAO SARPs).

Finally, when the Agency proposes and both advisory bodies agree that the subject may not require a wide consultation, the participation may be reduced. With this there could be a reduction in lead time of certain rulemaking tasks, without compromising necessary consultation. Such agreement should be reached at an early stage, e.g., already at the level of the BIS, where the safety or other risk is analysed, and where advisory bodies are consulted.

With respect to the last sentence, when consulting the advisory bodies on the intent to reduce participation where this is not already included in the working methods communicated under Art 3 (2), the Agency should also provide the reasons for that.

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:

#### RATIONALE

Art. 115(1)(c) BR requires that the procedure shall ensure that the Agency consults in accordance with a timetable and procedure. This is reflected in paragraph 3.

A new link is introduced to the BIS and EPAS, since in most cases the engagement and consultation of stakeholders is already discussed and decided there. Both, the BIS and EPAS are subject to consultation, so that stakeholders have the possibility to provide their comments and views on the Agency's proposal on how to engage and consult, already before the Agency initiates the development of the regulatory material.

- a. the most suitable timing to engage and/or consult;

#### RATIONALE

Engagement and/or consultation can happen at various points during the development of the regulatory material, or at the end of it. This may, for instance, depend on what participation is sought for: the regulatory options, the regulatory concept, the draft regulatory material. Also, there is a possibility to re-consult on the same subject (e.g., if a consultation has led to significant redraft of the regulatory proposal or has shown high controversy) or to consult separately on different aspects.

- b. the most suitable means and tools to achieve the widest possible participation; and

#### RATIONALE

The current consultation means and tools in MBD 18-2015 are quite prescriptive and always linked to a specific type of procedure. The experience of the Agency has shown that more flexibility is needed in order to effectively reach out to the right stakeholders with the right means and tools.



In order to achieve the widest possible participation, the Agency needs to consider what the purpose of the participation is (to inform, to enable feedback, to consult, to involve, to conduct a dialogue, ...) and based thereupon

- which type of participation is the best (engagement, consultation or a combination of both)
  - which stakeholders need to be engaged and/or consulted (the public, Member States, affected parties, interested parties, the advisory bodies, experts, specialists)
  - which tools achieve this best (e.g., notices of proposed amendments or other forms of presenting draft regulatory material, concept papers, questionnaires, workshops, consultation meetings, hearings, interviews).
- c. the length of the periods of this participation, which should be appropriate so as to enable the provision of meaningful comments.

#### RATIONALE

The appropriate length depends on the subject, the amount, and complexity of the draft regulatory material, the tools used to consult it, the form by which it is consulted, and on the possibilities of the stakeholder groups consulted to provide feedback. E.g., where a wide audience of stakeholders is consulted, or where the stakeholders are not able to react immediately (for instance where representative groups are being consulted, which need to involve their members), the consultation period needs to be longer than where a dedicated audience is consulted, which is already aware of the subject and prepared for commenting on the proposal.

For wide or even for public consultations on major subjects, a reasonable consultation period is 12 weeks; a recommended indicative minimum period for a public consultation is 4 weeks (see e.g., OECD Better Regulation Practices, or the European Commission's Better Regulation agenda). In some (rare) cases, where there is a need to develop regulatory material within a very short time period, the consultation may be reduced to a few days. There need to be objective reasons for this, which should be explained.

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 or 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.

#### RATIONALE

Last part ('and information about ...') added to the existing obligation in MBD 18-2015 in order to implement a recommendation from the European Ombudsman.

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.

#### RATIONALE

Art. 115(1)(c) BR requires that the procedure shall include an obligation on the Agency to give written response to the consultation process. This is reflected in paragraph 8.

The feedback has two dimensions: 1. (existing in today's procedure) feedback to commentators; language slightly more open as it is not only consultation; 2. (partially new) stemming from the *Better Regulation* agenda: transparency to the public on how stakeholder feedback was used. In practice, the two dimensions can be combined in one report.

The feedback needs to provide transparency as to which stakeholders contributed to the rule development, what contributions were made and how these contributions were considered. The form of feedback needs to consider the specificities of the rulemaking action and how effective feedback can be provided to create the necessary transparency. The feedback can be in form of detailed feedback, comment by comment, but it can also be in the form of a summary report.

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.

#### RATIONALE

This paragraph aims at an efficient preparation of the consultation of Member States in the EASA Committee and/or of Member State experts in the Commission Expert Group on Aviation Safety. The paragraph further specifies the function of the MAB as laid down in Article 3(1)(i) of the MB Decision 19-2015.

Before issuing an opinion, the Agency shall seek (and consider – in analogy – the principles laid down in paragraph 7) the advice from Member States whether there are any (remaining) substantially divergent views of the Member States. This advice is in addition to any engagement and/or consultation of the advisory bodies before. The advice from the MAB may be sought for example during plenary meetings, via dedicated meetings convened to seek such advice, or through a written procedure. The general engagement and consultation principles laid down in paragraph 3 should be considered by analogy; in particular, Member States should be given sufficient time to provide their advice, so to efficiently prepare the EASA Committee and/or the Expert Group.

### 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.

##### **RATIONALE**

Last part added to the existing obligation in MBD 18-2015 in order to implement a recommendation from the European Ombudsman.

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(9).

### 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.

FOR INFORMATION ONLY