

Management Board Decision

DECISION N° 18-2015

of 15 December 2015

replacing Decision 01/2012 concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications, acceptable means of compliance and guidance material ('Rulemaking Procedure')

THE MANAGEMENT BOARD OF THE EUROPEAN AVIATION SAFETY AGENCY,

Having regard to Regulation (EC) No 216/2008¹ of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, hereinafter referred to as the 'Basic Regulation', and in particular Article 52 thereof,

Having regard to Decision 01-2012 of the Management Board (MB) of 13 March 2012 concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications, acceptable means of compliance and guidance material (the 'Rulemaking Procedure'),

Taking into account the experience gained since that date as regards the efficiency and effectiveness of the Rulemaking Procedure,

Having regard to the proposals presented in WP06 at the MB meeting 02/2015 for less, better and timely regulations, which calls for new ways of developing and consulting regulations,

Having regard to the opinion of the Rulemaking Advisory Group (RAG) and the Safety Standards Consultative Committee (SSCC) on the draft text of this MB Decision,

Having regard to the opinion of the EASA Advisory Body (EAB) on the draft text of this MB Decision,

¹ Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1).

HAS ADOPTED THIS DECISION:

Section 1 — Basic principles and applicability

Article 1

Applicability and scope

This Decision prescribes the procedures for the development and issuing of opinions, certification specifications, acceptable means of compliance and guidance material by the Agency.

Article 2

Definitions

For the purpose of this Decision:

- ‘Rulemaking’ means the development and issuing of rules for the implementation of the Basic Regulation.
- ‘Rules’ comprises the following:
 - opinions on the scope and content of the Basic Regulation and its implementing rules, consisting of a draft regulation and an explanatory memorandum;
 - certification specifications (CSs) are technical standards adopted by the Agency indicating the means to demonstrate compliance with the Basic Regulation and its implementing rules, and which can be used by organisations for the purpose of certification;
 - acceptable means of compliance (AMC) are non-binding standards adopted by the Agency to illustrate the means to establish compliance with the Basic Regulation and its implementing rules; and
 - guidance material (GM) means non-binding material developed by the Agency that helps illustrate the meaning of a requirement or specification and is used to support the interpretation of the Basic Regulation, its implementing rules and AMC.
- ‘Preliminary impact assessment’ (PIA) means an assessment of:
 - the need to address a safety, environmental, level playing field and/or proportionality/efficiency issue, and its priority;
 - the identified, possible alternatives (e.g. safety promotion, focused oversight, research/studies and/or ‘do nothing’) to rulemaking in order to address an existing or new issue;
 - the potential safety, environmental, level playing field or proportionality/efficiency improvement compared to the estimated cost of the proposed measure.
- ‘Regulatory impact assessment (RIA)’ means an assessment of the benefits (in terms of safety, environmental, level playing field or proportionality/efficiency aspects) expected from the proposed rule as well as its implementation cost for national administrations and those subject to its provisions measured in relation to the option to not issue a rule. The aim of the RIA shall be to improve the quality

of regulations by helping ensure well-substantiated decisions and by clarifying the positive and negative safety, economic, environmental, social or other non-safety-related impacts of a proposed rule.

Section 2 — Rulemaking Programme

Article 3 **Programming**

1. The Executive Director shall establish annually a 5-year Rulemaking Programme after consultation with the Member States and the Interested Parties' Advisory Bodies, defined in Management Board Decision No 19-2015 and No 20-2015, including consultation with the European Commission.
2. When establishing the Rulemaking Programme, the following shall be taken into account:
 - (a) the objectives set out in Article 2 of the Basic Regulation;
 - (b) the criteria set out in Article 19 of the Basic Regulation;
 - (c) the relevant developments in European Union and international law;
 - (d) the European Commission's work programme for legislative and non-legislative tasks;
 - (e) the objective of harmonising Union rules with those of the European Union's main partners;
 - (f) the principles of performance-based regulations;
 - (g) identified safety hazards, risk assessment studies and other research activities undertaken by the Agency and other organisations, including the action areas identified in the European Plan for Aviation Safety (EPAS);
 - (h) the need to monitor the effectiveness of aviation safety and environmental protection requirements and to address any acute implementation problem as they fall within the Agency's remit;
 - (i) the experience gained from the implementation and standardisation process;
 - (j) the need to consider the results of air accident investigations in so far as they relate to aviation safety requirements;
 - (k) technological and scientific progress, new business models and the need for corresponding changes to aviation safety and environmental protection requirements;
 - (l) cross-domain issues stemming from strategic developments;
 - (m) the needs of emerging air traffic enhancement programmes from competent authorities in so far as they relate to aviation safety requirements that fall within the Agency's remit; and
 - (n) the regular review of the rules referred to in Article 3.9 of this Decision.
3. Any person or organisation may propose the development of a new rule or amendments to existing rules. The Executive Director shall consider such proposals in the context of the drafting and revision of the rulemaking programme. Proposals, including the identification of the proposer, the proposed new/amended text and the justification for the proposal, shall be submitted to the Agency and shall

be individually acknowledged. The Executive Director shall provide the proposer with a justification for his or her decision to act or not on the proposal.

4. Except in the case of paragraph 5, the rulemaking programme shall be supported by PIAs of the issues to be addressed. PIAs shall be consulted with the advisory bodies.
5. The Rulemaking Programme may include systematic rulemaking projects to address miscellaneous issues of non-controversial nature. A PIA shall not be required for these projects.
6. The Rulemaking Programme shall be aligned with the corresponding multi-annual work programme and shall be submitted to the Management Board as an annex to the multi-annual work programme.
7. The Executive Director shall adapt the Rulemaking Programme as appropriate in the light of unforeseen and urgent rulemaking needs. The European Commission and the advisory bodies shall be informed of any such adaptations.
8. The adopted Rulemaking Programme shall be published on the Agency's website.
9. The Executive Director shall conduct regular reviews of the impact of the rules issued under this Decision.

Section 3 — Rule development

Article 4 **Initiation**

1. Rulemaking projects shall be initiated in accordance with the priorities set out annually in the 5-year Rulemaking Programme.
2. The Executive Director shall draw up Terms of Reference (ToR) for each rulemaking project after consulting the advisory bodies. The ToRs, which shall be published on the Agency's website, shall include the following:
 - (a) a clear definition of the project and its scope;
 - (b) the process to be followed for the development of the project, including use of any of the special procedures referred to in Articles 14 to 16 and, if applicable, the estimated length of the consultation taking into account the assessment of the complexity and controversy of the project;
 - (c) the necessity to conduct a RIA;
 - (d) a timetable for the completion of the project;
 - (e) the type of the deliverable; and
 - (f) a concept paper, if developed in the case of a complex or controversial project.

In those cases where a rulemaking group is set up, the ToRs shall also include details on the composition of the group, its working methods and reporting requirements.

3. The Executive Director shall decide the working method, which includes but it is not limited to a drafting group or Agency resources, for the execution of each rulemaking project, taking into account the complexity and controversy of the project at hand and the need to draw upon the expertise of persons involved in the implementation of the new or amended rule. The Executive Director shall inform the advisory bodies about his or her decision.
4. When a rulemaking group is set up, the Executive Director shall determine its final composition, which shall draw upon the technical expertise available among national aviation authorities and, where necessary, interested parties, as well as in-house expertise.
5. The Agency shall provide rulemaking groups with administrative and logistical support necessary to perform their tasks, including the provision of standard working procedures. Rulemaking groups shall follow the working procedures adopted by the Executive Director, and in particular the following:
 - (a) elect a chair;
 - (b) reach consensus and resolve conflicts; and
 - (c) prepare the minutes.

Article 5

Regulatory impact assessment (RIA)

1. Further to the PIA referred to in Article 3.4, a RIA shall be part of the drafting of the rules, with the objective to ensure that their content is based on evidence and sound analysis, and to assess the need for a performance-based approach.
2. The RIA shall be conducted based on the principle of proportionate analysis: in-depth analysis to be performed for rulemaking projects with expected high impact, and light analysis for rulemaking projects with expected lower impact.
3. The Agency's advisory bodies and the rulemaking group members (when a rulemaking group is set up) shall support the development of the RIA by providing economic and other quantitative data.

Article 6

Drafting of rules

1. New rules or amendments to existing ones shall be drafted in accordance with the ToRs referred to in Article 4 of this Decision. The Executive Director may amend the ToRs as appropriate in the light of the progress of a given rulemaking project. The amended ToRs shall be published on the Agency's website.
2. For the drafting of rules, the following shall be taken into account:
 - (a) European Union law, and in particular the objectives and essential requirements set out in the Basic Regulation;
 - (b) ICAO Standards and Recommended Practices (SARPs);
 - (c) harmonisation objectives with other aviation authorities and international organisations in accordance with the applicable arrangements with third parties;
 - (d) the principles of performance-based regulations and related criteria for their implementation;

- (e) relevant findings and recommendations of air accident investigations;
 - (f) existing industry standards;
 - (g) timely implementation of the rules, taking into account translation delays;
 - (h) compatibility with existing rules and interfaces with other ongoing rulemaking projects;
 - (i) state of the art and best practices in aviation safety and environmental protection requirements;
 - (j) risk assessments conducted and available data;
 - (k) feedback from the implementation and standardisation process;
 - (l) cross-domain issues stemming from strategic, scientific and technological developments; and
 - (m) the outcome of the RIA being drafted, if applicable, as specified in the ToRs.
3. Upon completion of the drafting of the proposed rule, the Executive Director shall verify that the rule satisfies the objectives of the ToRs established for the rulemaking project and shall issue a notice of proposed amendment (NPA), which shall be published on the Agency's website, including the following information:
- (a) an explanatory note describing:
 - the development process, including the type and the estimated length of the consultation period, which may differ from the one indicated in the ToRs, as well as a planned date for the publication of the related comment-response document (CRD) and the final rule;
 - a summary of the proposed changes and full details of significant, contentious or interface issues identified during the drafting process; and
 - details of the situation with respect to Member States, ICAO SARPs and harmonisation with other aviation authorities or international organisations;
 - (b) the proposed draft rule;
 - (c) a RIA, if applicable, as specified in the ToRs;
 - (d) proposed actions to support implementation.
4. Each NPA shall be assigned a unique reference number.

Article 7 **Consultation**

1. Any person or organisation with an interest in or being affected by the draft proposed rule may submit their comment on the published NPA.
2. Consultees shall be informed that all comments on the NPA shall be treated in accordance with the rules on access to documents adopted by the Management Board according to Article 58 of the Basic Regulation.
3. In those cases where the NPA contains provisions to be applied by Member States, they shall be notified.

4. The public consultation period may vary from a minimum of 1 month to a maximum of 3 months.
5. During the public consultation period, the Executive Director may at the request of competent authorities of Member States or interested parties extend, in exceptional and duly justified cases, the public consultation period specified in the NPA. Such changes to the length of the public consultation period shall be published on the Agency's website.
6. Comments shall be forwarded on to the Executive Director and shall contain the following:
 - (a) identification of the commentator;
 - (b) NPA reference number; and
 - (c) position of the commentator with regard to the proposal (including justification for the position taken).

Article 8

Review of comments

1. With the objective to improve the quality of the Agency's rules and to ensure fair and appropriate treatment of all the comments received, the Executive Director shall ensure that comments are reviewed by appropriately qualified experts not directly involved in the drafting of the proposed rule together with Agency staff or a rulemaking group tasked with the drafting of the rule in question.

In the case of rulemaking projects with only negligible impact expected or systematic rulemaking projects addressing miscellaneous issues of non-controversial nature, the review of comments may be carried out without the need to involve additional experts.
2. Further consultation with consultees may be undertaken as necessary for the sole purpose of ensuring a better understanding of the comments received.
3. The Executive Director shall review the comments received and shall publish the outcome of the consultation on the Agency's website. The CRD shall include the following:
 - (a) a list of all parties who commented on the rule in question; and
 - (b) a summary of the comments received and the Agency's responses thereto.
4. If, based on the number or complexity of the comments received, the Executive Director is unable to publish the CRD within the timescale indicated in the NPA, amendments to the timescale shall be published on the Agency's website.
5. If the comments received during the consultation period indicate major objections to the proposed rule, or if the outcome of the review of the comments is that the revised text differs significantly from that presented at the beginning of the consultation process, the Executive Director shall consider further consultation with the stakeholders.
6. If the comments received from Member States in the context of Article 7.4 of this Decision indicate major objections to the proposed rule, the Executive Director shall consult the Member States Advisory Group to discuss the rule further. In those cases where additional consultation results in further disagreement regarding the rule, the Executive Director shall include in the CRD the results of this consultation and the impact and consequences of his or her decision regarding the issue at stake.

Article 9

Adoption and publication

1. The Executive Director shall issue his or her decision in respect of the rule in question together with the CRD.
2. Rules issued by the Executive Director shall be published on the Agency's website together with an explanatory memorandum and, in the case of opinions, a revised RIA if the final text differs significantly from that presented at the beginning of the consultation.

Article 10

Ex post evaluation

The Rulemaking Programme shall include projects for ex post evaluation of existing rules with the objective to review feedback from implementation and assess the rules' efficiency and effectiveness. Ex post evaluation should identify which rules could be clarified, simplified, updated or possibly repealed. It should also assess whether a performance-based approach could be applied.

Section 4 — Final provisions

Article 11

Cooperation with third countries and international organisations

Cooperation with third countries and international organisations in the field of rulemaking shall be dealt with as specified in the arrangements and agreements concluded in accordance with Articles 12, 27 and 66 of the Basic Regulation.

Article 12

Access to documents

Access to documents retained by the Agency in relation to rulemaking activities shall be governed by the practical arrangements that are established in accordance with Article 58 of the Basic Regulation.

Article 13

Retention of documents

1. In respect of the Agency's rulemaking and related procedures, such documentation shall be retained so as to enable the Agency to provide justification for its decisions and to show that the appropriate procedures have been followed. In particular, for each rule and the subsequent amendments thereto, the Executive Director shall ensure that the following are retained in a central archive:
 - (a) the formal request for the initiation of a rulemaking project;
 - (b) the PIA initiating the rulemaking project;

- (c) ToRs, including the group composition when the working method foresees a rulemaking group;
 - (d) the published NPA, including an explanatory note and a RIA where applicable;
 - (e) the CRD(s);
 - (f) minutes of rulemaking group meetings;
 - (g) documents submitted to the rulemaking group.
2. The Executive Director shall ensure that a full set of all published rules is retained for an indefinite period.

Article 14

Special rulemaking procedure: advance notice of proposed amendment (A-NPA)

1. In those cases where the programming, initiation or drafting of a rule has revealed a need for a broader discussion of new concepts or for further information/data prior to the drafting of an NPA, the Executive Director may initiate an A-NPA public consultation phase prior to the consultation described in Article 7 of this Decision. The issuing of an A-NPA should be justified by the existence of, and the need to study possible solutions for, an appropriately substantiated case or to seek the view of stakeholders on new developments or concepts, which require either the preparation of future rulemaking activities or are part of the development of a complex rulemaking project.
2. The A-NPA shall be published for the purpose of public consultation on the Agency's website. The Executive Director shall determine the length of the public consultation period. A review of comments shall be performed and published to record in all cases the results of the consultation and when appropriate to state the Agency's intentions following the A-NPA phase. The A-NPA shall contain an explanatory note (including a justification for following the A-NPA process) and:
 - (a) an outline of the new rule or amendment to an existing one; or
 - (b) various options for a new rule or amendment to an existing one and soliciting comments on the different options presented therein.
3. The A-NPA procedure shall not replace the NPA procedure. An A-NPA is not necessarily followed by an NPA.

Article 15

Special rulemaking procedure: direct publication

1. By way of derogation from Articles 6.3, 7, 8 and 9.1 of this Decision, for rulemaking projects with expected negligible impact, or for rulemaking projects addressing urgent safety issues which require immediate reaction or addressing issues which have been already widely consulted through the A-NPA procedure or other consultation processes, the Executive Director may decide to issue his or her decision in respect of the rule in question without the need for an NPA public consultation. The rule shall be published as described in Article 9.2.
2. The issuing of the decision shall be preceded by a consultation of its draft version with the advisory bodies.

Article 16

Special rulemaking procedure: accelerated procedure

1. By way of derogation from Articles 5, 6.3 and 7 of this Decision, for rulemaking projects with expected negligible impact, or rulemaking projects addressing issues of non-controversial nature or affecting a limited group of stakeholders, the Executive Director may decide that:
 - (a) a RIA is not required. A rationale for the rulemaking project shall complement the NPA or the proposed new or amended existing rule;
 - (b) an NPA does not need to be developed and consulted. In this case, only a proposed new or amended existing rule needs to be developed and consulted;
 - (c) it is sufficient to consult the NPA or the proposed new or amended existing rule with the affected stakeholders only. This focused consultation may take the form of workshops, technical experts' meetings, ad hoc consultation of the Agency's advisory bodies, or surveys.
2. The issuing of the decision shall be preceded by a consultation of its draft version with the advisory bodies.

Article 17

Executive Director

1. The Executive Director shall ensure that the Rulemaking Procedure prescribed in this Decision is appropriately applied to all the Agency's rulemaking activities.
2. After consulting the advisory bodies, the Executive Director shall establish the necessary internal procedures for the implementation of this Decision, in particular with regard to Articles 3.2, 3.7, 3.8, 4.5, 5.3, 6.3, 8.1, 8.3, 8.5, 8.6, 13, 14, 15 and 16 thereof. These procedures shall be published on the Agency's website.

Article 18

Entry into force

This Decision shall enter into force on the day of its publication on the Agency's website.

Done in Cologne, 15th of December 2015

[Signed]

PEKKA HENTTU
Chair of the Management Board