

European Aviation Safety Agency

**DECISION OF THE MANAGEMENT BOARD¹
AMENDING AND REPLACING DECISION 08-2007
CONCERNING THE PROCEDURE TO BE APPLIED BY THE AGENCY
FOR THE ISSUING OF OPINIONS, CERTIFICATION SPECIFICATIONS
AND GUIDANCE MATERIAL ('RULEMAKING PROCEDURE')**

THE MANAGEMENT BOARD,

Having regard to Regulation (EC) No 216/2008² 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 8-07 of the Management Board of 13/06/2007 concerning the procedures to be followed by the Agency to develop and issue the rules necessary for the implementation of the Basic Regulation,

Taking into account experience gained since this date in the functioning of the Rulemaking Procedure, in particular with regard to its efficiency and effectiveness,

Having regard to the proposals included in the final report on the review of the Rulemaking Process as presented in WP04 to MB 04/11 and adopted by the Management Board in its meeting of 14 December 2011,

Having regard to the Opinion of the EASA Advisory Body,

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, acceptable means of compliance, certification specifications and guidance material by the Agency.

¹ Adopted at MB 01/2012 on 13 March 2012,

² 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). Regulation as last amended by Regulation (EC) No 1108/2009 of the European Parliament and of the Council of 21 October 2009 (OJ L 309, 24.11.2009, p. 51).

Article 2 – Terminology and definitions

For the purposes of this Decision:

- 'Rulemaking' means the development and issuance of rules for the implementation of the Basic Regulation.
- 'Rules' comprises the following:
 - opinions concerning the scope and content of the Basic Regulation and its implementing rules, consisting of a draft regulation and an explanatory memorandum;
 - acceptable means of compliance (AMC) are non-binding standards adopted by the Agency to illustrate means to establish compliance with the Basic Regulation and its implementing rules;
 - certification specifications (CS) are technical standards adopted by the Agency indicating means to show compliance with the Basic Regulation and its implementing rules and which can be used by organisations for the purpose of certification; and
 - guidance material (GM) means non-binding material developed by the Agency that helps to illustrate the meaning of a requirement or specification and is used to support the interpretation of the Basic Regulation, its implementing rules and AMC.
- 'Regulatory Impact Assessment (RIA)' means an assessment of the safety or environmental benefit 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 regulation by helping to ensure that decisions are well substantiated, by clarifying the positive and negative safety, economic, environmental, social or other non-safety impacts of a proposed rule.

Section 2 – Rulemaking Procedure

Article 3 – Programming

1. The Executive Director shall establish annually a 4-year Rulemaking Programme after consultation with the Safety Standards Consultative Committee, the Rulemaking Advisory Group and the Thematic Advisory Groups, defined in Articles 9 and 10 of this Decision, including consultation with the Commission.
2. The Rulemaking Programme shall take account of:
 - i. the objectives set out in Article 2 of the Basic Regulation;
 - ii. the criteria for implementing rules described in the Basic Regulation;
 - iii. relevant developments in European Union and international law;
 - iv. the Commission's work programme for legislative and non-legislative tasks;
 - v. the objective of harmonisation of Union rules with those of the Union's main partners;

- vi. identified safety hazards, risk assessment studies and other research activities undertaken by the Agency and other organisations, including the regular review of the rules referred to in Article 3.9;
- vii. the need to monitor the effectiveness of aviation safety and environmental protection requirements and to correct acute implementation problems arising there in so far as they fall within the Agency's remit;
- viii. experience gained from the standardisation process;
- ix. the need to take due account of the results of air accident investigations in so far as they relate to aviation safety requirements;
- x. technological and scientific progress and the need for corresponding changes in aviation safety and environmental protection requirements; and
- xi. 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.

3. Any person or organisation may propose the development of a new rule or an amendment thereto. The Executive Director shall consider such requests in the context of the drafting and revision of the Rulemaking Programme. Proposals, including the identification of the proposer, the proposed text and the justification for the proposal shall be sent to the Agency and shall be individually acknowledged. The Executive Director shall provide the proposer with justification for his or her decision on whether to act on his or her proposal.

4. Except in the case of paragraph 5, the Rulemaking Programme shall be supported by a Preliminary Regulatory Impact Assessment of each of the issues to be addressed.

5. The Rulemaking Programme may include systematic tasks to address miscellaneous issues of non-controversial nature. A Preliminary Regulatory Impact Assessment will not be required for these tasks.

6. The Rulemaking Programme shall be aligned with the corresponding annual work programme and shall be incorporated, as an annex, in the annual work programme to be submitted to the Management Board for adoption.

7. The Executive Director shall adapt the rulemaking programme as appropriate in the light of unforeseen and urgent rulemaking demands. The Commission, the Safety Standards Consultative Committee, the Rulemaking Advisory Group and the Thematic Advisory Groups shall be informed of any such changes.

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.

Article 4 – Initiation

1. Rulemaking activities shall be initiated in accordance with the rulemaking priorities set out annually in the 4-year Rulemaking Programme.

2. The Executive Director shall draw up Terms of Reference for each rulemaking task after consulting the Safety Standards Consultative Committee, the Rulemaking Advisory Group and/or the Thematic Advisory Groups. The Terms of Reference, which shall be published on the Agency's website, shall include the following:

- i. a clear definition of the task;
- ii. the process to be followed for the development of the task, including the estimated length of the public consultation period taking into account the assessment of the complexity and controversy of the task;
- iii. the necessity to conduct a Regulatory Impact Assessment;
- iv. a timetable for completion of the task;
- v. the format of the deliverable; and
- vi. a concept paper, if developed in the case of a complex or controversial task.

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

3. The Executive Director shall choose the working method, which includes but it is not limited to the use of a drafting group or Agency resources, for the fulfilment of each rulemaking task, taking into account the complexity and controversy of the task at hand and the need to draw upon the expertise of persons involved in the implementation of the rule envisaged. This decision shall be taken after consulting the Safety Standards Consultative Committee, the Rulemaking Advisory Group and/or the Thematic Advisory Groups.

4. When a drafting group is convened, the Executive Director shall determine its exact composition, which shall draw upon technical expertise available among national authorities and, where necessary, interested parties, as well as within the Agency itself.

5. The Agency shall provide drafting groups with the administrative and logistical support necessary for the fulfilment of their tasks, including the provision of standard operating procedures to be adapted as necessary by the groups themselves according to their specific circumstances. Drafting groups shall follow the working methods adopted by the Executive Director, which shall include in particular the following:

- i. chair elections;
- ii. obtaining consensus and resolution of conflicts; and
- iii. preparation of minutes.

Article 5 – Drafting

1. New rules or amendments thereto shall be drafted in accordance with the Terms of Reference referred to in Article 4 of this Decision. The Executive Director may amend the Terms of Reference as appropriate in the light of progress of the rulemaking task. The Executive Director shall inform the Safety Standards Consultative Committee, the Rulemaking Advisory Group and the Thematic Advisory Groups of any such changes.

2. The drafting of rules shall take into account the following:

- iv. European Union law, in particular the objectives and essential requirements as set out in the Basic Regulation;
- v. ICAO Standards and Recommended Practices;
- vi. harmonisation objectives with other authorities and international organisations in accordance with the applicable arrangements with third parties;

- vii. relevant findings and recommendations of air accident investigations;
- viii. timely implementation of the proposed rules, taking into account translation delays;
- ix. compatibility with existing rules;
- x. state of the art and best practices in aviation safety and environmental requirements;
- xi. risk assessments performed and available data;
- xii. scientific and technological developments; and
- xiii. the regulatory impact of the rules being drafted, if applicable, as specified in the Terms of Reference.

3. Upon completion of the drafting of the proposed rule, the Executive Director shall verify that the rule satisfies the Terms of Reference established for the rulemaking task and shall publish a Notice of Proposed Amendment (NPA) on the Agency's website, including the following information:

- i. an Explanatory Note describing:
 - the development process and the next steps, including the length of the public consultation period, which may differ from the one indicated in the Terms of Reference, as well as a proposed date for the publication of the Comment Response Document;
 - 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 Standards and Recommended Practices and relative to harmonisation with other authorities or international organisations;
- ii. the proposed rule;
- iii. a Regulatory Impact Assessment, if applicable, as specified in the Terms of Reference.

4. As regards tasks with only negligible impacts expected, or systematic tasks addressing miscellaneous issues of non-controversial nature, it is sufficient for the Notice of Proposed Amendment to contain a justification for the task and the proposed new or amended rule.

5. Each NPA shall be assigned a unique reference code.

Article 6 — Consultation

1. Any person or organisation with an interest in the rule under development shall be entitled to comment on the basis of the published NPA, without discrimination on the basis of nationality.

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 under Article 58 of the Basic Regulation.

3. In those cases where the NPA contains provisions to be applied by the Member States, copies thereof shall be transmitted to them.

4. The consultation period may vary from a minimum of 1 month to a maximum of 3 months.

5. During the consultation period, the Executive Director may, in exceptional and strictly justified circumstances, extend the consultation period specified in the NPA at the request of competent authorities of Member States or interested parties. Such changes to the length of the consultation period shall be published on the Agency's website.

6. Comments shall be forwarded to the Executive Director and shall contain the following elements:

- i. identification of the commentator;
- ii. NPA reference code; and
- iii. position of the commentator, relative to the proposal (including justification for the position taken).

Article 7 – Review of comments

1. With the objective of improving the quality of the Agency's measures and ensuring fair and appropriate treatment of all 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 drafting group tasked with the drafting of the rule in question.

In the case of tasks with only negligible impacts expected or systematic tasks addressing miscellaneous issues of non-controversial nature, the comment review may be carried out without the need to involve additional expertise.

2. Further consultation with consultees may be undertaken as necessary for the sole purpose of ensuring a better understanding of the comments submitted.

3. The Executive Director shall review the comments received from the consultees and will publish the outcome on the Agency's website. The Comment Response Document shall include the following:

- i. a list of all parties commenting on the rule in question; and
- ii. 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 Comment Response Document by the deadline specified in the NPA, amendments to this deadline shall be published on the Agency's website.

5. If the comments received during the public consultation period indicate major disagreements with the proposed rule, or if the result of the review of the comments is that the revised text differs significantly from that circulated 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 6.3 of this Decision indicate major objections to the proposed rule, the Executive Director shall consult the Rulemaking Advisory Group to discuss the rule further. In those cases where additional consultation results in continuing disagreement regarding the rule, the Executive Director shall include in the Comment Response Document the results of this consultation and the impact and consequences of his/her decision regarding the issue at stake.

Article 8 – Adoption and publication

1. The Executive Director shall issue his/her decision in respect of the rule in question together with the Comment Response Document.
2. Rules issued by the Agency shall be published on the Agency's website together with an explanatory memorandum and, in the case of opinions, an updated Regulatory Impact Assessment, if the final text differs significantly from that circulated at the beginning of the consultation process.

Section 3 – Final provisions

Article 9 – Safety Standards Consultative Committee (SSCC)

1. The Executive Director shall be assisted by the Safety Standards Consultative Committee (SSCC).
2. The Committee shall be made up of representatives of persons and organisations directly subject to the Basic Regulation, to implementing rules, to certification specifications or to guidance material without discrimination on the basis of nationality. Its exact composition shall be determined by the Executive Director taking account of the requirement to balance representation with efficiency.
3. The tasks of the Committee shall be as follows:
 - i. providing advice on the content, priorities and execution of the Agency's Rulemaking Programme, including commenting on Preliminary Regulatory Impact Assessments and Terms of Reference;
 - ii. providing advice on the setting up and composition of drafting groups as necessary in relation to specific rulemaking tasks;
 - iii. providing advice on the development and use of regulatory tools and concepts in so far as they relate to the work of the Agency including, in particular, recommendations on risk assessment analyses, Regulatory Impact Assessments and other tools to be employed in rulemaking;
 - iv. adoption of recommendations addressed to the Executive Director on the consistency of the Rulemaking Programme and the need to adapt existing rules to technological and commercial evolution/progress;
 - v. adoption of recommendations addressed to the Executive Director on the need to adapt existing rules in the light of experience gained in their application; and
 - vi. providing advice as appropriate in the context of ongoing efforts to improve the Agency's rulemaking processes and structures.
4. The Committee shall retain independence and shall be entitled to make recommendations in those fields covered by paragraph 3 of this article and in all aspects related to the rulemaking activities of the Agency. It shall therefore adopt its rules of procedure and elect a chair in consultation with the Executive Director.
5. The Agency shall provide the Committee with the administrative and logistical support necessary for the fulfilment of its tasks.

6. All aspects of the Committee's work, including membership, procedures, meeting agendas, minutes and related documentation, shall be published on the Agency's website.

*Article 10 – Rulemaking Advisory Group
and Thematic Advisory Groups*

1. The Executive Director shall be assisted by a Rulemaking Advisory Group (RAG) and a number of Thematic Advisory Groups (TAGs).

2. These groups shall be made up of representatives of the national authorities responsible for applying the Basic Regulation and its implementing rules and the Commission.

3. The Regulatory Advisory Group shall provide advice on strategic rulemaking issues, such as:

- i. the overall priorities of the Rulemaking Programme;
- ii. horizontal or controversial issues, including the provision of advice on concept paper;
- iii. the Agency's rulemaking processes and structures;
- iv. in the case of substantial difference in the views of the Member States with regard to a specific rulemaking task, or in relation to outstanding technical issues prior to the adoption of the Opinion;
- v. the understanding of the provisions of the Basic Regulation.

4. The Thematic Advisory Groups shall each focus on a certain area within the competence of the Agency. Their tasks, within their relevant area, shall be to:

- i. provide advice on the content, priorities and execution of the Agency's Rulemaking Programme, including commenting on Preliminary Regulatory Impact Assessments and Terms of Reference;
- ii. provide advice on the composition of drafting groups as necessary in relation to specific rulemaking tasks;
- iii. provide guidance on the way forward for rulemaking tasks related to complex technical issues. For this purpose TAG members may be requested to meet with SSCC sub-committees to exchange information and views;
- iv. provide input on the implementation of rules and to assess the need for further rulemaking activities;
- v. provide input on the coherence between existing rules and proposed rules;
- vi. upon request of the Rulemaking Advisory Group, provide advice on any specific technical aspects.

5. The groups shall retain independence and shall be entitled to make recommendations in those fields covered by paragraph 3 and 4 of this article and in all aspects related to the rulemaking activities of the Agency. The groups shall determine their working methods and shall be chaired by the Executive Director.

6. All aspects of the groups' work, including membership, procedures, meeting agendas, minutes and related documentation, shall be published on the Agency's website.

*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 concluded in accordance with Articles 12, 27 and 66 of the Basic Regulation.

Article 12 – Access to documents

Access to documents held by the Agency in relation to rulemaking activities shall be governed by the practical arrangements to be 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 maintained so as to enable the Agency to demonstrate justification for its decisions and to show that the correct procedures have been followed. In particular, for each rule and subsequent amendments thereto, the Executive Director shall ensure that the following items are retained in a central file:

- i. the submission initiating the NPA;
- ii. Terms of Reference, including the group composition when the working method foresees a drafting group;
- iii. the published NPA, including Explanatory Note and Regulatory Impact Assessment where applicable;
- iv. the Comment Response Document(s);
- v. notes of drafting group meetings;
- vi. documents submitted to the drafting group and discussed under specific items.

2. The Executive Director shall ensure that a full set of all published rules is retained indefinitely.

Article 14 – Special procedures

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 Advance Notice of Proposed Amendment (A-NPA) pre-consultation phase prior to the consultation described in Article 6 of this Decision. The issuance 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 necessitates either the preparation of future rulemaking work or is part of the development of a complex task.

The A-NPA shall be published for public consultation on the Agency's website. The Executive Director shall determine the length of the consultation period. A review of comments will 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. The A-NPA shall contain an Explanatory Note (including a justification for using the A-NPA process) and either of the following:

- i. an outline of the new rule or amendment thereto; or
- ii. various options for a new rule or amendment thereto and soliciting comments on the different options presented therein.

The A-NPA procedure shall not replace the NPA procedure. An A-NPA is not necessarily followed by an NPA.

Article 15 – Executive Director

1. The Executive Director shall ensure that the Rulemaking Procedure prescribed in this Decision is correctly applied to all Agency rulemaking activities.
2. After consulting the Safety Standards Consultative Committee, the Rulemaking Advisory Group and the Thematic Advisory Groups, 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, 7.1, 7.3, 7.5, 7.6, 13 and 14 thereof. These procedures shall be published on the Agency's website.

Article 16 – Entry into force

This Decision shall replace Decision MB/8/07 of 13.06.2007 when it enters into force upon publication on the Agency's website.

Done at Cologne,

[Signed]

For Michael Smethers
Chair of the Management Board
Maxime Coffin Vice Chair