

European Aviation Safety Agency

DECISION OF THE MANAGEMENT BOARD AMENDING AND REPLACING DECISION 7-03 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) N° 1592/2002¹ of the European Parliament and of the Council of 15 July 2002 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 to article 43 thereof.
- Having regard to the Decision 7-03 it adopted on 27/06/2003 to specify 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 as regards the issuing of guidance material and Advance Notices of Proposed Amendments (A-NPA).
- Having regard to the Opinion of the EASA Advisory Body²,

HAS ADOPTED THIS DECISION:

¹ Regulation (EC) No 1592/2002, *OJ L 240*, 7.9.2002, p. 1. Regulation as last amended by Regulation (EC) No 1701/2003, *OJ L 243*, 27.9.2003, p. 5.

² E-mail of 04 May 2007

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 and guidance material by the Agency.

Article 2 – terminology and definitions

For the purposes of this Decision:

- 'Rulemaking' shall mean 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;
 - certification specifications (including airworthiness codes and acceptable means of compliance) to be used in the certification process; and
 - guidance material, which is non-binding material that helps to illustrate the meaning of an implementing rule or a certification specification and which does not provide presumption of compliance when used in the certification process.
- 'Regulatory impact assessment' shall mean 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. 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 an annual rulemaking programme in consultation with the Safety Standards Consultative Committee and the Advisory Group of National Authorities.

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 article 5.5 of the Basic Regulation;
 - iii. relevant developments in European Community and international law;
 - iv. the objective of harmonisation of Community rules with those of the Community's main partners;
 - v. risk assessment studies and other research activities undertaken by the Agency and other organisations, including the regular review of rules referred to in article 3.9;
 - vi. the need to monitor the effectiveness of aviation safety and environmental protection requirements and to correct acute implementation problems arising there from in so far as they fall within the Agency's remit.
 - vii. the need to take due account of the results of air accident investigations in so far as they relate to aviation safety requirements;
 - viii. technological and scientific progress and the need for corresponding changes in aviation safety and environmental protection requirements; and
 - ix. 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. The rulemaking programme shall be supported by a preliminary regulatory impact assessment of each of the rules envisaged and an analysis of the priority accorded to each task taking into account these preliminary regulatory impact assessments and the resources at the Agency's disposal.

5. As regards guidance material, a task shall be systematically included in the annual rulemaking programme. The Safety Standard Consultative Committee and the Advisory Group of National Authorities will be invited to propose possible new or amended guidance material together with the proposed working method for their development. Preliminary regulatory impact assessment will not be required.

6. The finalised rulemaking programme shall be incorporated, as an annex, in the annual work programme 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 Safety Standards Consultative Committee and the Advisory Group of National Authorities shall be informed of any such changes.

8. The adopted rulemaking programme shall be published in the Agency's official publication.

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 in the annual rulemaking programme.

2. The Executive Director shall draw up terms of reference for each rulemaking task after consulting the Safety Standards Consultative Committee and the Advisory Group of National Authorities. The terms of reference, which shall be published in the Agency's official publication, shall include the following:

- i. a clear definition of the task;
- ii. a timetable for completion of the task; and
- iii. the format of the deliverable.

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

3. The Executive Director shall choose between the use of a drafting group or Agency resources for the fulfilment of each rulemaking task, taking into account the complexity 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 and the Advisory Group of National Authorities.

4. As regards guidance material, the drafting shall be done by the Agency except when the importance and complexity of the guidance material justifies the use of a group. Terms of reference are not a pre-requisite to launch the drafting of new or amended guidance material except if a group is used for drafting. In the latter case paragraph 2 shall apply.

5. 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.

6. 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 adopt their working methods, in particular the following:

- i. Chair/Secretary elections;
- ii. obtaining of consensus and resolution of conflicts; and
- iii. the 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 with the rulemaking task. The Executive Director shall inform the Safety Standards Consultative Committee and the Advisory Group of National Authorities of any such changes.

2. Drafting of rules shall take into account the following:

- i. European Community law, in particular the objectives and essential requirements as set out in the Basic Regulation;
- ii. ICAO Standards and Recommended Practices;
- iii. harmonisation objectives with other authorities and international organisations in accordance with applicable arrangements with third parties;
- iv. relevant findings and recommendations of air accident investigations;
- v. timely implementation of the proposed rules, taking into account translation delays;
- vi. compatibility with existing rules;
- vii. state of the art and best practices in aviation safety and environmental requirements
- viii. scientific and technological developments; and
- ix. the regulatory impact of the rules being drafted.

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) in the Agency's official publication, including the following information:

- i. the proposed rule;
- ii. an explanatory note describing the development process;
- iii. full details of significant or contentious or interface issues identified during the drafting process;
- iv. details of the situation with respect to ICAO Standards and Recommended Practices and relative to harmonisation with other Authorities or International Organisations; and
- v. a full Regulatory Impact Assessment.

4. As regards guidance material, it is sufficient that the Notice of Proposed Amendment contains a justification (including a paragraph showing that the material complies with the definition of guidance material) and the proposed new or amended guidance material.

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 47 of the Basic Regulation.

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

4. The consultation period shall be 3 months from the date of NPA publication.

5. The Executive Director may, prior to the start of the consultation period, specify a shorter or longer consultation period to that specified in paragraph 4. This decision shall take account of the potential impact and complexity of the rules envisaged and the opinions of the Safety Standards Consultative Committee and the Advisory Group of National Authorities. Notification of the length of this revised period shall be published at the same time as the NPA in question.

6. During the consultation period, the Executive Director may, in exceptional and strictly justified circumstances, extend the consultation period specified in paragraphs 4 and 5 at the request of competent authorities of Member States or interested parties. Such changes to the length of the consultation period shall be published in the official publication of the Agency.

7. 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 Agency 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 the Agency staff or drafting group tasked with the drafting of the rule in question. Further consultation with consultees may be undertaken as necessary for the sole purpose of securing a better understanding of comments submitted.

2. The Executive Director shall review the comments received from consultees and publish details in the Agency's official publication within 3 months of the expiry of the consultation period. This comment response document shall include the following:

- i. a list of all parties commenting on the rule in question; and
- ii. a summary of comments received and the Agency's responses thereto.

3. As regards guidance material, the review of comments will be done by the Agency or the group, which drafted the NPA, without the need for review by experts not directly involved in the drafting of the proposed guidance material. A comment response document shall be established.

4. If, based on the number of comments received, the Executive Director is unable to publish the comment response document referred to in paragraph 2 by the deadline specified, he or she shall publish an amended timetable for the rulemaking process.

5. If the result of the review of comments is that the revised text differs significantly from that circulated at the start of the consultation process, the Executive Director shall consider a further consultation round in accordance with this Decision.

6. If the comments received from national authorities in the context of article 6.3 of this Decision indicate major objections to the proposed rule, the Executive Director shall consult the Advisory Group of National Authorities 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 no earlier than 2 months following the date of publication of the comment response document in order to allow sufficient time for consultees to respond to its contents.
2. Rules issued by the Agency shall be published in the Agency's official publication, together with an explanatory memorandum.
3. As regards guidance material, the minimum time between the publication of the comment response document and the adoption and publication of the rule specified in paragraph 1 is not applicable.

Section 3 – final provisions

Article 9 – Safety Standards Consultative Committee

1. The Executive Director shall be assisted by a Safety Standards Consultative Committee.
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 and amendments thereto;
 - 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 insofar 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 of existing rules to take account of 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 its operation.

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

Article 10 – Advisory Group of National Authorities

1. The Executive Director shall be assisted by an Advisory Group of National Authorities.

2. The Group shall be made up of one person per Member State who shall represent those national authorities responsible for applying the Basic Regulation and its implementing rules.

3. The tasks of the Group shall be as follows:

- i. providing advice on the content, priorities and execution of the Agency's rulemaking programme and amendments thereto;
- 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 insofar 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 of existing rules to take account of 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;
- vi. providing advice as appropriate in the context of ongoing efforts to improve the Agency's rulemaking processes and structures; and
- vii. providing advice to the Executive Director pursuant to the procedure described in article 7.6.

4. The Group 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. The Group shall determine its working methods and shall be chaired by the Executive Director.

5. All aspects of the Group's work, including membership, procedures, meeting agendas, minutes and related documentation, shall be published in the Agency's official publication.

Article 11 - co-operation with third countries and international organisations

Co-operation with third countries and international organisations in the field of rulemaking shall be dealt with as specified in arrangements concluded in accordance with articles 9, 18 and 55 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 47 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. the published NPA including justification and regulatory impact assessment;
- iii. the comment response document(s);
- iv. terms of reference of the drafting group or authorising statement to Agency officials;
- v. notes of drafting group meetings;
- vi. documents submitted to the drafting group and discussed under specific items; and
- vii. correspondence files.

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 a NPA, the Executive Director may initiate an Advance Notice of Proposed Amendment 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, which

necessitates either to prepare future rulemaking work or as part as the development of a complex task.

The A-NPA shall be published for comments in the Agency's official publication. 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 an NPA procedure. An A-NPA is not automatically followed by an NPA.

Article 15 - transitional arrangements

For the issuing of decisions in respect of rules directly derived from the adaptation of existing JAA regulatory material, the rulemaking procedure shall be amended as follows:

- i. The provisions of article 4, 5, 7 and 8.1 shall not apply.
- ii. The length of the consultation period described in article 6.4 shall be of six weeks' duration. In justified circumstances the Management Board may decide to extend this period on a case-by-case basis to allow for further consultation.
- iii. Consultees shall be provided with a reasoned acknowledgement of their comments.

Article 16 – 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 and the Advisory Group of National Authorities, 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, 4.6, 5.3, 7.1, 13 and 14 thereof. These procedures shall be published in the Agency's official publication.

Article 17 – entry into force

This Decision shall replace Decision MB/7/03 of 27.06.2003 when it enters into force upon publication in the Agency's official publication.

Done at Cologne on 11 June 2007,

THE CHAIRMAN
THILO SCHMIDT
