How to use this template

Editorial remark:

Text displayed in square brackets, in italics, and highlighted in grey (*[italics]*) serves as guidance material for the RO and shall be deleted before publication.

Text displayed in roman and highlighted in grey (text) shall be replaced by the Rulemaking Officer. New text shall be: font: Verdana; font size: 10; typeface: roman; highlight: none.

European Aviation Safety Agency

NOTICE OF PROPOSED AMENDMENT

NPA 2011-XX

C. Regulatory Impact Assessment

task title

RMT.XXXX (OLD.XXX)

[Front page for internal use only] [1]

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0.1	Draft	

Authorisation:			
	Name	Signature	Date
Prepared by	Rulemaking Officer		
Peer review by	Name		
RIA review by	Name		
Authorised by	Name		

[1] This front page is for internal use and traceability. It will be removed when the RIA is added to the NPA as Appendix C.1.

Table of contents

1 Process and consultation

[Describe briefly how the RIA was developed. Was a Pre-RIA available? If there was a rulemaking group, who were the representatives and when were the ToR agreed? Was there any other input, e.g. through a study?]

2 Issue analysis and risk assessment

[Check if a Pre-RIA is available for this issue. If it exists, you can copy-paste the text from the corresponding section 'issue analysis' and amend it if required.]

2.1 What is the issue and the current regulatory framework?

[Explain the issue that the proposal is intended to address. Describe the nature of the problem and its extent.]

[What are the underlying root causes/drivers of the issue?]

[Specify the reasons for, and constraints to, the action. Possible reasons may be the ICAO requirements; high level policy decisions; service experience; incident/accident data; supporting research data; scientific or technical progress; international harmonisation; regulatory improvement, etc. Possible constraints may be conflicting policies, established law that limits the scope of action, etc.]

[Are there any implementation problems identified? Is there an uneven implementation across EASA Member States?]

[What is the current regulatory framework? What is the current legislation applicable to this issue?]

[Develop a baseline scenario, i.e. How will the situation develop (deteriorate?) if the regulatory framework is not changed or if other measures are taken?]

[Why does the problem need to be addressed by the Agency?]

[Identify the assumptions made.]

2.2 Who is affected?

[Which sectors, groups and stakeholders are affected by the issue? Give additional information on the cover sheet. Do the current situation and regulatory conditions raise public concern or stir controversy among the general public? Do the current situation and regulatory conditions raise stakeholders' concern or stir controversy among stakeholders?]

[Types of aircraft, systems, constituents or equipment affected. Give additional information on the cover sheet, e.g. more detailed breakdown, number of products affected, etc.]

2.3 What are the safety risks?

[If the current situation implies uncertainty about possible harmful events, please specify in this section the safety risks involved. If applicable, please identify the risks.]

[Describe the safety hazards identified. Hazards are defined as:

'Conditions, objects or activities with the potential of causing injuries to personnel, damage to equipment or structures, loss of material, or reduction of ability to perform a prescribed function.'][What information is available on the probability/frequency of the problem? Quote available data and sources the proposal is based on. As regards safety issues, probability is defined as the likelihood that an unsafe event or condition may occur.]

[What is the scale/severity of the problem? As regards safety, severity can be defined as the possible consequence of an unsafe event or condition, taking as a reference the worst foreseeable situation.]

*[For **safety risks**, the following risk matrix can be used: [2]]*

Table 1: Risk index matrix

Probability of occurrence		**Severity of occurrence**				
		Negligible	**Minor**	**Major**	**Hazardous**	**Catastrophic**
		1	2	3	5	8
Extremely improbable	1					
Improbable	2					
Remote	3					
Occasional	4					
Frequent	5					

3 Objectives

The overall objectives of the Agency are defined in Article 2 of Regulation (EC) No 216/2008 (the Basic Regulation). This proposal will contribute to the overall objectives by addressing the issues outlined in Section 2. The specific objective of this proposal is therefore: …

[Define a clear and specific objective directly related to the issue analysis. The specific objective should address the issue identified and its root causes. In most cases the objective has been defined in the Pre-RIA and in the Terms of Reference of the rulemaking task.]

[2] See Annex for further details on the risk matrix.

4 Identification of options

[What are the possible options for meeting the objectives and tackling the problem?

Any options for dealing with the issue shall be identified. The option of 'doing nothing' (option 0) shall be considered as the reference scenario. Non-rulemaking options should be considered wherever possible. Although it is important to attempt to identify a range of options, only those reasonably practicable shall be further analysed.

*Very often you will find a large number of possible technical options. For a RIA you **do not** need to analyse each and every one of them, but you need to perform a screening of the options — possibly with the help of stakeholders — to reduce the number of options to a practical level. These options should include the ones where you expect impacts with the highest significance (e.g. in terms of safety improvement, costs, and impacts on people's personal or professional lives). Frequently these are also the options that trigger the most intense discussions in rulemaking groups.*

A pre-screening and bundling of options may be necessary. Which options have been discarded at an early stage and why? Refer to the pre-screening criteria (e.g. poor effectiveness or inconsistency with other objectives and policies). Be particularly specific and precise for discarded options enjoying significant support among stakeholders.]

Table 2: Selected policy options

Option No	Description
0	Baseline option (No change in rules; risks remain as outlined in the issue analysis.)
1	Specify as appropriate
2	Specify as appropriate
3	Specify as appropriate
…	…

5 Methodology and data requirements

5.1 Applied methodology

[If a full RIA was conducted, please describe the applied methodology (e.g. Cost-Benefit Analysis, Multi-Criteria Analysis). The RIA team in R.6.2 can provide standard texts to describe the applied methodology.

There are several possibilities to analyse the impacts and to compare the options:

— *Cost-Benefit Analysis (CBA). If all the required data are available, then a CBA can be performed which quantifies all impacts in monetary terms: e.g. safety in terms of avoided fatalities and injuries, compliance costs for the industry, environmental costs. The outcome can be expressed in terms of Net Present Value or Benefit Cost Ratio.*

— *Cost-Effectiveness Analysis (CEA). If the (safety) target is given and the choice of options is limited to choosing the cheapest one.*

— *Multi-Criteria Analysis (MCA). If no full monetization is possible, this tool allows comparing all options by scoring them against a set of criteria. Each criterion needs to receive a certain weight.*

— *If the implementation of the previous methodologies failed (no provision of sound justifications), the least is to quantify a range of case studies.*

For the most recent RIAs the Agency applied the Multi-Criteria Analysis (MCA); for examples check the 'Best practice' module on the RIA pages (http://intranet.easa.local/R/PSU/RIA/Pages/Best-practiceandfeedback.aspx)]

5.2 Data requirements

[What are the data requested for the analysis of the options? Are these data publicly available? If yes, indicate the sources; if no, indicate how they were collected. What is the methodology used to reach the different estimates?

If data have to be estimated, indicate the underlying assumptions set out.]

6 Analysis of impacts

[The evaluation shall identify all possible impacts resulting from implementing the considered options on all concerned sectors. The below chapters can be combined or omitted if, for example, there is no social impact expected for any of the options.

The evaluation shall identify the sectors of the civil aviation community (including authorities) within the regulated domain which will be affected and, if appropriate, the number of organisations, individuals and/or aircraft affected by the options. These sectors include manufacturers, operators, maintenance, crew, organisations, training organisations, consumers, aircraft owners, etc. If a specific category of persons, small businesses, and regional groups are likely to be differently affected, this shall be identified for further evaluation and quantification. Only those sectors that are directly affected by the intended measure need to be considered.

Please pay particular attention to the following parameters:

— *Specify uncertainties and how impact may be affected by changes in the parameters.*

— *Include impacts within the EU and outside the EU.*

— *Specify which impacts are likely to change over the time and how: this is very important in order to be able to estimate the weight of the transitional period before a rule is fully implemented.*

— *Use the baseline situation described in Section 2 as a reference: How can each option contribute to improving the baseline situation and to what extent? How can the risks identified in 0 be mitigated by this option?*

— *What are the potential obstacles to compliance costwise?]*

6.1 Safety impact

[All safety impacts of the considered option shall be identified and, wherever possible, quantified. The evaluation shall include an identification of hazards and a classification of risks taking into account the probability of occurrence and the severity of effects in relation to the baseline option as described in Chapter 2. If there is no expected impact on safety, a statement to that effect shall be made.]

6.2 Environmental impact

[Aircraft noise and emissions.]

6.3 Social impact

[Social impacts may include:

Impacts on employment and on labour market;

Working hours and working conditions;

Movement of personnel;

Health;

Social inclusion and protection of particular social groups;

Gender equality, equal treatment and equal opportunities, non-discrimination;

Access to social protection.]

6.4 Economic impact

[Compliance costs/savings for the industry, licence holders, staffing, or consumers?

Administrative burden.

Is there a possibility for simplification?

Implementation costs (transitional period with additional costs impacts)/savings for the NAAs.

Do the current situation and regulatory conditions induce a competitive disadvantage for certain economic entities?]

6.5 Proportionality issues

[Impacts on SMEs and/or on General Aviation.

Impacts in terms of regional distribution: Is a region particularly negatively affected by the proposals?

Are there any sectors that will be particularly negatively affected by the proposal?]

6.6 Impact on regulatory coordination and harmonisation

[Are there any implementation problems expected for the proposed options?

Is there an option where national action is considered instead of EASA rulemaking? Is the issue under Community competence?

Is any other EU legislation affected?

Is there a danger of duplication at national level?

Does the proposal have an impact on Member States' obligations towards ICAO?

Does the proposal harmonise the requirements with Third Country requirements?

Are there any potential obstacles and incentives to compliance?]

7 Conclusion and preferred option

7.1 Comparison of options

[The options are to be compared and a final assessment shall be made stating the main reasons for choosing the preferred option recommended. Discuss why the preferred option was chosen and what the main drivers behind this choice are. If a CBA was used, an overview table of costs and benefits will be provided here. If an MCA was used, an overview table is to be presented with scores of the respective options. For further guidance consult the RIA pages on the EASA intranet (http://intranet.easa.local/R/PSU/RIA/Pages/GettingStarted.aspx) and contact the RIA team in R.6.2.]

7.2 Sensitivity analysis (optional)

[Describe the main uncertainties on the outcomes of the options.]

Annex A: Acronyms and definitions

Annex B: References

Annex C: Risk assessment

ICAO **defines** safety as the state in which the risk of harm to persons or property damage is reduced to, and maintained at or below, an acceptable level through a continuous process of hazard identification and risk management.

Thus, risk assessment is a key element for managing safety. **Risk is expressed in terms of predicted probability and severity of the consequences of a hazard taking as a reference the worst foreseeable situation.**

In order to define the elements 'probability' and 'severity', the following tables were developed based on the ICAO framework.

Table 3: Probability of occurrence [3]

Definition	Value	Description
Frequent	5	Likely to occur many times (has occurred frequently). Failure conditions are anticipated to occur one or more times during the entire operational life to each aircraft within a category.
Occasional	4	Likely to occur sometimes (has occurred infrequently). Failure conditions are anticipated to occur one or more times during the entire operational life to many different aircraft types within a category.
Remote	3	Unlikely, but possible to occur (has occurred rarely). Those failure conditions that are unlikely to occur to each aircraft within a category during its total life, but that may occur several times when considering a specific type of operation.
Improbable	2	Very unlikely to occur. Those failure conditions not anticipated to occur to each aircraft during its total life, but which may occur a few times when considering the total operational life of all aircraft within a category.
Extremely improbable	1	Almost inconceivable that the event will occur. For rulemaking proposals aimed at CS-25, CS-29 or CS-23 (commuter) aircraft, the failure conditions are so unlikely to occur that they are not anticipated to occur during the entire operational life of the entire fleet. For other categories of aircraft, the likelihood of occurrence may be greater.[4]

[3] These categories need to be applicable to a wide range of safety issues and are taken from the ICAO Safety Management Manual. The description is harmonised with CS-25. Note that these descriptions are indicative only and may have to be adjusted to different rulemaking tasks depending on subsector of aviation.

[4] The category 'extremely improbable' here can also include cases where the probability cannot be quantified as 10^{-9}.

Table 4: Severity of occurrences

Definition	Value	Description
Catastrophic [5]	8	Multiple deaths (three and more) and equipment destroyed (hull loss).
Hazardous	5	A large reduction of safety margins. Maximum two fatalities. Serious injury. Major equipment damage.
Major	3	A significant reduction of safety margins. Serious incident. Injury of persons.
Minor	2	Nuisance. Operating limitations. Use of emergency procedures. Minor incident.
Negligible	1	Little consequences.

Table 5: Risk index matrix

Probability of occurrence		**Severity of occurrence**				
		Negligible	**Minor**	**Major**	**Hazardous**	**Catastrophic**
		1	2	3	5	8
Extremely improbable	1	**1**	**2**	**3**	**5**	**8**
Improbable	2	**2**	**4**	**6**	**10**	**16**
Remote	3	**3**	**6**	**9**	**15**	**24**
Occasional	4	**4**	**8**	**12**	**20**	**32**

[5] Note that the severity category 'Catastrophic' was attributed the value of 8. This has been done in order to distinguish a 'Catastrophic/Extremely improbable' case from a 'Negligible/Frequent' case and give a higher weight to catastrophic events. The former is considered to be of medium significance whereas the latter is of low significance as the potential outcome is limited.

Frequent	5	**5**	**10**	**15**	**25**	**40**

Table 6: Description of the different risk indices

Risk index		**Description** [6]
16–40	High significance	Unacceptable under the existing circumstances.
15	Medium or High significance	For non-complex aircraft this would result in a medium significance issue. For CAT with complex motor-powered aircraft this would result in a high significance issue.
7–14	Medium significance	Tolerable based on risk mitigation by the stakeholders and/or rulemaking action.
1–6	Low significance	Acceptable, but monitoring or non-rulemaking action required.

[6] The descriptions are based on the ICAO Safety Management Systems Handbook. However, as the SMS system is geared towards operators and not regulators, the descriptions were adjusted to better reflect EASA's needs.