

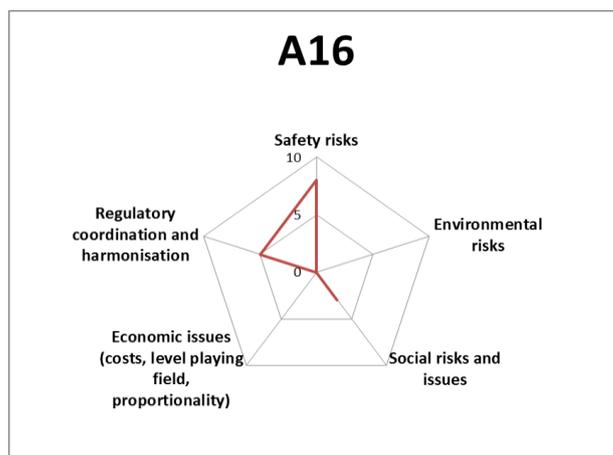


European Aviation Safety Agency — Rulemaking Directorate

Preliminary Regulatory Impact Assessment

Title

RMT.XXXX (OLD.XXX) — XX/XX/201X



For explanation on the Pre-RIA methodology, see Explanatory Note.

EXECUTIVE SUMMARY

This proposal addresses a safety/environmental/social/economic/proportionality/regulatory coordination issue related to ...

The specific objective is to ... [mitigate the risks linked to .../maintain a high level of safety for .../achieve a smooth transition .../provide cost-efficient rules in the field of ...].

[There is a safety recommendation ... The proposal is linked to the EASp safety action No .../ICAO State Letter ...]

The safety risk level is considered to be high/medium/low.

The resulting Pre-RIA score is ... See radar chart and Chapter 3 for driving factors.

Based on this Pre-RIA, rulemaking is [(not) recommended]. [The following non-rulemaking action is proposed: ...] [The proposed rulemaking action is considered complex/controversial, because ...]

Applicability		Process map	
Affected regulations and decisions:	[See List of abbreviated rules & regulations]	Rulemaking lead:	R2/R3/R4/R5
Affected stakeholders:	[Indicate also whether Member States are affected]	Concept Paper:	Yes/No
Driver/origin:	[Safety; environment; level playing field; proportionality and cost-effectiveness; legal obligation (ICAO, EU, clarity of rules)]	Terms of Reference:	[Year/Quarter/TBD]
Reference:	[SR No ...; EASp Action No ...]	Rulemaking group:	Yes/No
		RIA type:	Full/Light/None
		Technical consultation during NPA drafting:	Yes/No/TBD
		Duration of NPA consultation:	1/2/3 months
		Review group:	Yes/No/TBD
		Focused consultation:	Yes/No/TBD

Contributors (internal)

For internal use	Name	Version No	Date
Prepared by:	Rulemaking Officer ¹	0.1	
Peer-reviewed by:	Name		
Approved by:	Section Manager/HoD		
Reviewed by:	RIA team R.6.2		
Peer-reviewed by:	C, S, E experts assigned to the task (if applicable)		
Approved by:	Process owner alternative action (if applicable) ²		
Approved by:	HoD		

Internal coordination

[Specify if this Pre-RIA needs to be discussed at ISC level and if the following ToR would need to be presented at ISC. This should apply only to complex/controversial tasks as defined in Chapter 6. Specify in case managerial guidance on the broad direction of the task was received.]

Resource estimate (at the time of drafting; may be subject to change)

In order to deliver this rulemaking task, the following resource estimate has been conducted:

Resource	Requirement
Rulemaking Directorate Rulemaking Officer RIA team Editing team Legal	[Please specify in terms of hrs/project] 50 hours for Light RIA, 100 hours for full RIA
C/S/E Directorates focal points (if applicable)	[Please specify the name of the project focal point appointed by C, S or E and the hours allocated to each person]
NAA/NSA staff for Rulemaking Group (if applicable)	[Please specify in terms of hrs/project]
Industry staff for Rulemaking Group (if applicable)	[Please specify in terms of hrs/project]
Study	[Yes/No]
Duration (from publication of ToR to publication of Opinion/ED Decision)	[Please specify number of years]

¹ If R staff or C, S or E experts were involved, please add their names as appropriate.

² Only applicable if alternative non-rulemaking action is proposed in the Pre-RIA which may impact other Agency Directorates.

1. Introduction

The purpose of this document is to give guidance on two critical questions regarding the rulemaking proposal:

- Is rulemaking necessary? Or should the issue better be addressed by other means (e.g. research, awareness-raising campaigns, etc.)?
- If rulemaking is recommended, what should be the priority of this proposal?

The answer to these questions will be based on the issue analysis in Chapter 2 and the baseline assessment in Chapter 3 below. Chapter 5 discusses if rulemaking is required and which options are available.

2. Issue analysis and preliminary safety risk assessment

2.1. What is the issue and the current regulatory framework?

[What is the origin of the task?]

[Explain the issue/problem that the proposal is intended to address. Describe the nature of the problem and its extent. If the main issue is safety, refer to Section 2.3.]

[What are the underlying root causes/drivers of the issue/problem? Possible causes/drivers are listed in the questionnaire in Chapter 3.]

[What is the current regulatory framework? What is the current legislation applicable to this issue? Is it part of a larger framework (e.g. SES)?]

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

[How will the situation develop in the future if the regulatory framework is not changed? For example, no action may be required right now because there are only few operations but, if the rules are not changed, there will be problems in the future due to increase in operations.]

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2.2. Who is affected?

[Which sectors, groups and stakeholders are affected by the issue? Give additional information in the applicability box.]

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

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2.3. What are the safety risks (probability and severity)?³

[If the current situation implies uncertainty about possible harmful events, please specify the safety risks involved in this section. 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 on which the proposal is based. As regards safety issues, probability is defined as the likelihood that an unsafe event or condition may occur.]

³ This section is only to be filled in if safety risks are identified. For environmental risks, please discuss under Section 2.1.

[How effective are the existing mitigating measures, including rules, as described under the regulatory framework?]

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 situation⁴.]

[If no risks were identified, simply state: 'No risks identified'.]

[For safety risks, the following risk matrix can be used as the main outcome of the matrix will determine the level of risk (high, medium, low)⁵. The outcome of this assessment will be used to answer the first question in Chapter 3 below.]

Based on the above, the risk is considered extremely improbable/catastrophic. The level of risk is, thus, medium.

Table 1: Safety risk matrix⁶

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

⁴ For further guidance on hazards and risks, please consult the ICAO Safety Management Manual ([Doc 9859 Safety Management Manual – 3rd Edition - 2012](#)).

⁵ For further guidance on the risk matrix, see Explanatory Note.

⁶ Enter 'X' in the appropriate box and see the Explanatory Note for the resulting risk index 'high', 'medium' or 'low'. The risk level may vary depending on the aviation domain.

3. Baseline assessment (Pre-RIA scoring)

The following questionnaire provides a quick assessment of the current situation taking into account the objectives of Regulation (EC) No 216/2008 and the feedback loops.

Type of risks and issues <u>under the current regulatory conditions</u>	Estimated significance			
	None (0)	Low (1)	Medium (3)	High (5)
3.1. Safety risks				
Q-1. Have safety risks been identified in Section 2.3? <i>Reasoning: See 2.3.</i>	X			
Q-2. Has a safety recommendation been addressed to the Agency? <i>Reasoning:</i>	X			
Q-3. Is the issue linked to a safety action from EASp? <i>Reasoning:</i>	X			
Q-4. Has a related recommendation from Standardisation been issued? <i>Reasoning:</i>	X			
Q-5. Has a future challenge from research, technological advancements, business evolution or new best practices been identified? <i>Reasoning:</i>	X			
3.2. Environmental risks				
Q-6. Have environmental risks been identified in terms of gaseous emissions (greenhouse gases/local air quality) or noise? <i>Reasoning:</i>	X			
3.3. Social risks and issues				
Q-7. Have the EASA rules created social risks or issues, e.g. in terms of limiting free movement of persons, health issues, licencing issues? <i>Reasoning:</i>	X			
3.4. Economic risks including level playing field and proportionality				
Q-8. Have excessive costs of regulatory framework been identified for authorities, industry, licence holders, or consumers? <i>Reasoning:</i>	X			
Q-9. Has a competitive disadvantage been identified for certain economic entities (obstacles on the level playing field)? <i>Reasoning:</i>	X			
Q-10. Has an issue for General Aviation (GA)/SMEs been identified contradicting the guidelines in the European GA strategy ⁷ ? <i>Reasoning:</i>	X			
3.5. Regulatory coordination and harmonisation (including legal requirements)				
Q-11. Have implementation problems or regulatory burden been identified? <i>Reasoning:</i>	X			
Q-12. Has a difference or non-compliance with ICAO Standards been identified, or a State Letter been received? <i>Reasoning:</i>	X			
Q-13. Has a need for harmonisation with third countries (e.g. FAA, TCCA) been identified? <i>Reasoning:</i>	X			
Pre-RIA score				
Significance level			Significance points	
A = high safety risk,			(Total from questions 1–13)	

⁷ http://intranet.easa.local/R/Important%20Files/European%20General%20Aviation%20Safety%20Strategy_final_edit.pdf

Type of risks and issues <u>under the current regulatory conditions</u>	Estimated significance			
	None (0)	Low (1)	Medium (3)	High (5)
B = medium safety risk or other high/medium risk, C = low or no significance.				
A/B/C				X

4. Objectives of the proposal

The objectives of the European Union in the field of civil aviation are defined in Article 2 of Regulation (EC) No 216/2008⁸ (hereinafter referred to as the 'Basic Regulation'). This proposal will contribute to the achievement of these objectives by addressing the issues outlined in Chapter 2.

The specific objective of this proposal is, therefore, to ...

[Define a list of clear specific objectives directly related to the issue analysis. A specific objective shall be to solve the issue identified, e.g. to mitigate the safety risks linked to .../to maintain a high level of safety for .../to achieve a smooth transition from national/ICAO rules to European common requirements in the field of .../to provide cost-efficient rules in the field of ...]

It cannot be simply 'to change CS/AMC/GM'.]

5. Options, preliminary impacts and recommended action

5.1. Options

In order to achieve the above objective, the options below were identified. These options are non-exhaustive, preliminary and indicative and, thus, do not prejudge future rulemaking activities which may contain different options. Only the baseline option (no regulatory change) is mandatory.

[The most important question at this stage is if there should be rulemaking or not. If there are non-rulemaking options that can achieve the objective, they should be preferred. Especially tasks which received a 'C' score should be carefully evaluated for the need to start a rulemaking task. Consider that an option could be related to different rulemaking disciplines (e.g. Initial Airworthiness or Flight Standards). Different options could also be based on where they are placed in the hierarchy of rules, e.g. Option 1: IR only; Option 2: High-level requirements in IR; the rest in AMC or GM.]

Option	Description
0	No rulemaking (baseline option; issues remain as outlined in Chapter 3).
1	Please specify as many options as necessary.
2	Please specify as many options as necessary.
3	Please specify as many options as necessary.

[Which of the options identified is most likely to (best) achieve the objective?]

5.2. Preliminary impacts identified

[Highlight the important expected outcomes per option on:
safety,

⁸ Regulation (EC) No 216/2008 of the European Parliament and 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), as last amended by Commission Regulation (EU) No 6/2013 of 8 January 2013 (OJ L 4, 9.1.2013, p. 34).

environment,

economic,

social, and

regulatory harmonisation.

[An overview table of pros and cons can be used here.]

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5.3. Recommended action

Based on the issue analysis and the Preliminary Regulatory Impact Assessment, the Agency concludes:

Rulemaking action required
Yes/No

The following alternative action is proposed [if applicable]:

[Enter reasoning and alternative action proposed, if applicable. Describe who will be responsible for the follow-up.]

6. Complexity and controversy

[If rulemaking action was proposed] The proposed rulemaking action is considered complex and/or controversial for the following reasons:

[Enter reasoning, if applicable.]

The proposed rulemaking action may be complex when:

- *it affects several aviation domains; or*
- *it affects several Parts and CSs; or*
- *it proposes a new rulemaking concept; or*
- *it deals with a new subject, needs research, and data are not yet available; or*
- *cooperation is needed with other bodies apart from the Agency (e.g. coordination with the EC on the implementation of SES.)*

Controversial may be when:

- *there is (expectedly) no consensus among stakeholders on the issue to be addressed (i.e. on the concept, the approach, the interpretation of the Basic Regulation, etc.); or*
- *it has significant economic or social impacts.*

The working method and process map on the cover page were developed on the basis of this assessment of complexity and controversy.

7. Annex I: References

7.1. Affected regulations

...

7.2. Affected decisions

...

7.3. Reference documents

[Reference documents include regulatory material, which is relevant to the task, but will not be changed by the task. Reference documents also include non-regulatory material.]

8. Annex II: RIA data needs

[If a light or full RIA is envisaged, provide a preliminary list of indicators/data to be collected from Sections 2.1 and 2.2. This will give a hint to the RIA team of the future data needs and will enable the distribution of questionnaires, if relevant, to stakeholders at an early stage.]