



Rules development	Doc #	PR.RPRO.00001-002
	Approval Date	26/08/2013

Rules development

PR.RPRO.00001-002

	Name	Validation	Date
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**DOCUMENT CONTROL SHEET****Reference documents****a) Contextual documents**

Commission regulation template - Template of Commission Regulation. Annex of EASA opinion

FAA-EASA Rulemaking cooperation guidelines

MB Decision 01-2004 - Decision of the Management Board of 3rd of February 2004 concerning the arrangements to be applied by the Agency for public access to documents

MB Decision 01-2012 - Decision of the Management Board 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")

Regulation (EC) 1049/2001 - Regulation (EC) of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents

Regulation (EC) 216/2008 - Regulation of European Parliament and of Council of 20 Feb. 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) 1592/2002 and Directive 2004/36/EC

Regulation (EC) 45/2001 - Regulation of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data

b) Internal documents

FO.RPRO.00010 - Rulemaking group composition

FO.RPRO.00028 - Contact details of candidate for rulemaking group

FO.RPRO.00071 - SDol of members of rulemaking group

TE.GEN.00401 - ED Decision

TE.RPRO.00034 - Notice of Proposed Amendment (NPA)

TE.RPRO.00036 - Opinion of EASA

TE.RPRO.00037 - Rulemaking Terms of Reference

TE.RPRO.00039 - Cover letter to DG MOVE to accompany Opinions

TE.RPRO.00040 - Advance Notice of Proposed Amendment

TE.RPRO.00053 - Executive Briefing Note on Decisions and Opinions

TE.RPRO.00058 - Explanatory Note to ED Decision

TE.RPRO.00064 - Comment Response Document

TE.RPRO.00065 - Concept Paper

UG.RPRO.00033 - Rulemaking style guide

WI.IMS.00044 - Archiving and filing of rulemaking deliverables

WI.RPRO.00043 - Handling of EASA Forms

WI.RPRO.00044 - Determination of the memberships of Rulemaking groups

WI.RPRO.00045 - Rule of procedure for Rulemaking Groups

WI.RPRO.00048 - SSCC Rule of Procedure

WI.RPRO.00059 - Register of EASA Rules

WI.RPRO.00063 - RAG and TAGs rule of procedure

WI.RPRO.00066 - Project management of rulemaking tasks

WI.RPRO.00068 - Rules development

WI.RPRO.00069 - Rule of procedure for stakeholders-led Rulemaking tasks



**Abbreviations/Definitions**

AMC: Acceptable Means of Compliance
CdT: Centre de Traduction
CRD: Comment Response Document
CRT: Comment Response Tool
CS: Certification Specifications
DG MOVE: European Commission's Directorate-General for Mobility and Transport
ED: Executive Director
EN: Explanatory Note
FAA: Federal Aviation Authority
TCCA: Transport Canada Civil Aviation
GC: Group Composition
GM: Guidance Material
MB: Management Board (Decision)
MS: Member State of the EU
NAA: National Aviation Authority
NPA: Notice of Proposed Amendment
RAG: Rulemaking Advisory Group
RIA: Regulatory Impact Assessment
RMP: Rulemaking Programme
RO: Rulemaking Officer
SSCC: Safety Standards Consultative Committee
TAG: Thematic Advisory Group
ToR: Terms of Reference
WI: Work Instruction

Log of issues

Issue	Issue date	Change description
001	25/03/2010	First issue. Migration of R.P002-00 and related QMS work instructions
002	26/08/2013	Issue 002. Update to reflect the outcomes of the review of the rulemaking process. Applicable as of 1 September 2013.
		Issue 003. Migration of Quality documents in compliance with Convergence project.





INTRODUCTION

Purpose and scope

The Rules development starts from the publication of the 4-year Rulemaking programme and finishes with the Executive Director's adoption of a Decision and/or an Opinion. The Opinions are submitted to the Commission for further processing, while the Decisions (CS, AMC and GM) are directly published and applicable.

The major milestones of the Rules Development are:

- the publication of the Terms of Reference (ToR) of the rulemaking task;
- the publication of the Notice of Proposed Amendment (NPA), which contains the draft rule and the Regulatory Impact Assessment (RIA);
- the public consultation of the NPA; and
- the publication of the Decision and/or Opinion with the Comment Response Document (CRD), which includes the comments received during the public consultation together with the Agency's responses.

This procedure is applied for each rulemaking project contained in the 4-year Rulemaking Programme.

Legal framework

MB Decision 01/2012 prescribes the procedure for the development and issuing of Opinions, Certification Specifications and Guidance Material by the Agency, as defined in the EASA Regulation Article 43.

This procedure covers MB 01/2012 Articles 4 "Initiation", 5 "Drafting", 6 "Consultation", 7 "Review of Comments", 8 "Adoption and publication", 11 "Co-operation with Third Countries and International Organisations", 12 "Access to documents" and 13 "Retention of documents" and the requirement of the EASA Regulation to translate its Opinions as set out in Article 23.

Basic Principles

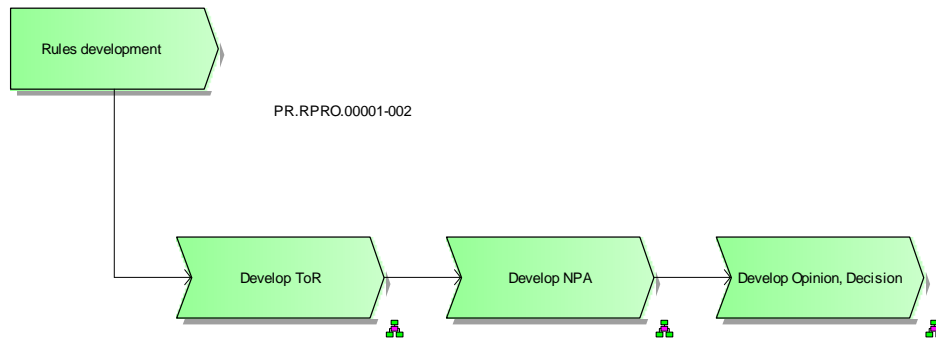
The Rules development follows different steps: initiation and development of the ToR, drafting and consultation of the NPA, analysis of comments and final review for adoption and publication of the Decision and/or Opinion.



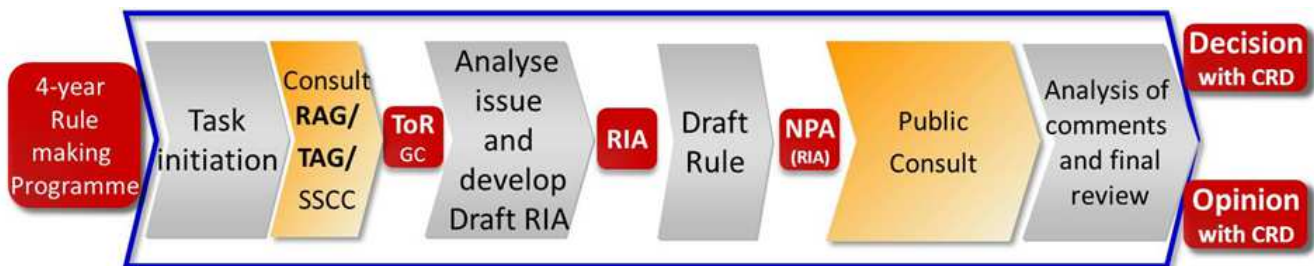


Structure of process charts

Rules development

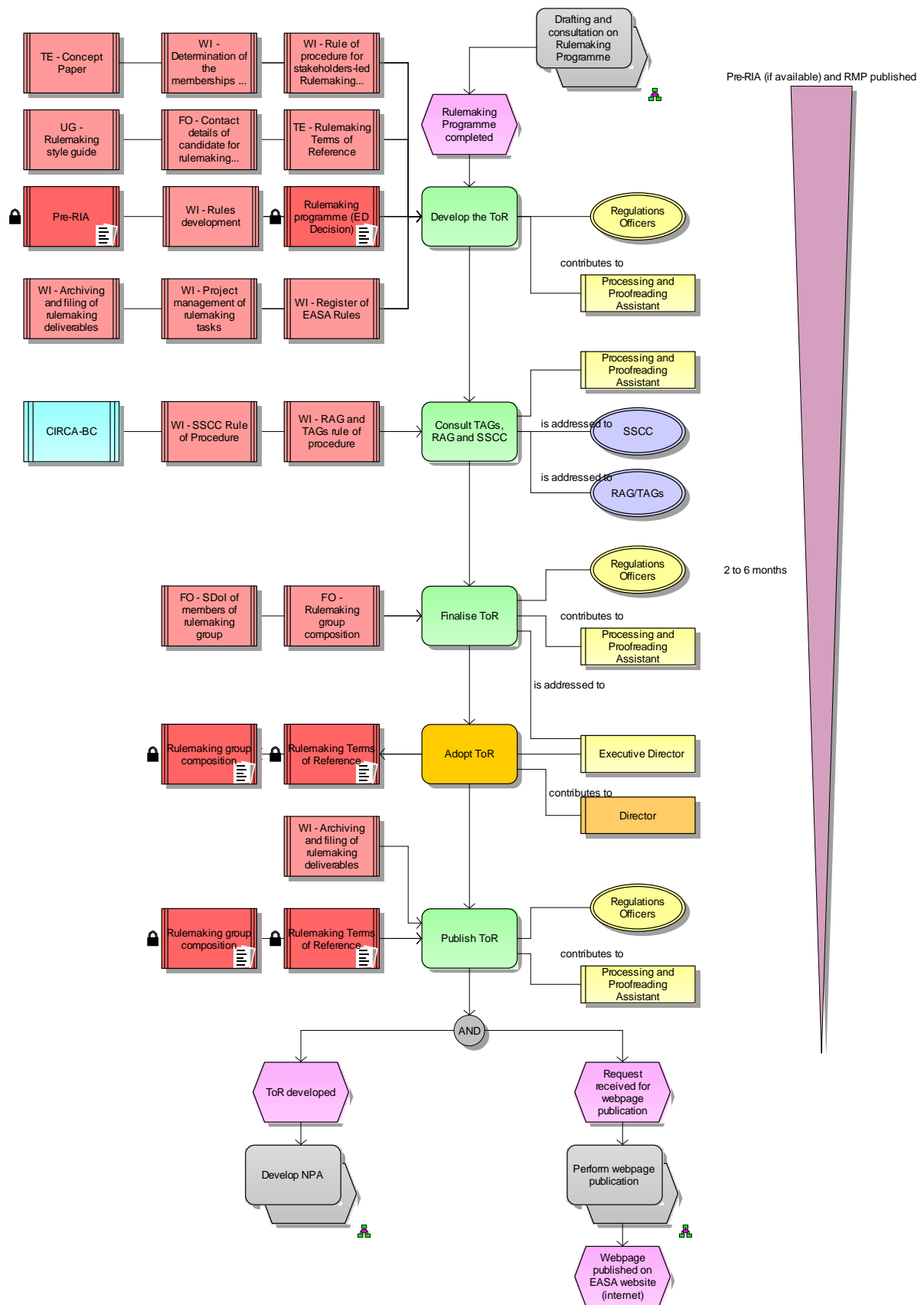


Overview of the main steps and milestones of the rules development process





Develop ToR





Activity	Description to the process activity
Develop the ToR	<p>The Terms of Reference (ToR) define the scope of the task and the way it is to be performed. The ToR include:</p> <ul style="list-style-type: none">— a clear definition of the task and its main objectives, including affected rules and stakeholders;— the content and format of the final deliverable (i.e. Opinion or Decision, if already predefined);— process-related information to describe the working method and the steps to be followed for the task's execution (the process map);— the baseline planning (i.e. milestones and timelines for the task's completion);— an estimation of expected internal resources (in hrs). <p>The starting point for the development of the ToR is the Pre-RIA (if available) and the published 4-year Rulemaking Programme (which includes planned start and end date of the rulemaking task).</p> <p>In those cases where a rulemaking group was proposed as the working method in the Pre-RIA or as part of the published 4-year Rulemaking Programme, the ToR also include the profile of the drafting group's members and an estimation of the expected number of the rulemaking group's meetings.</p> <p>In case of very complex or controversial tasks, the Agency's approach may be established with the use of a Concept Paper. In most cases, the decision to prepare a Concept Paper is made at the Pre-RIA stage by the Regulations Officer (RO) in consultation with the line management.</p> <p>Archiving is ensured according to the WI.IMS.00044 Archiving and filing of rulemaking deliverables.</p>
Consult TAGs, RAG and SSCC	<p>The draft ToR are (together with the concept paper, if applicable) submitted to the advisory bodies (i.e. RAG, TAGs and SSCC) for a commenting period which varies from 2 to 4 weeks.</p>
Finalise ToR	<p>After consulting the advisory bodies, and eventual amendments following the consultation, the ToR is ready to be adopted and published on the Agency's website.</p>
Adopt ToR	<p>Before publication, the ToR is circulated by the Processing and Proofreading Assistant for adoption by ED, who can delegate to the relevant director.</p>
Publish ToR	<p>Once adopted, the ToR + GC are sent to EASA webmaster for publication on the Agency's website and a notification email is sent to IETC secretariat, RAG/TAGs/SSCC and FAA/TCCA (if applicable).</p> <p>Archiving is ensured according to the WI.IMS.00044 Archiving and filing of rulemaking deliverables.</p>

Internal Process Interfaces

Drafting and consultation on Rulemaking Programme
Develop NPA
Perform webpage publication





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Activity	Description to the process activity
Develop NPA (including RIA)	<p>The drafting phase results in the Notice of Proposed Amendment (NPA), which includes:</p> <ul style="list-style-type: none"> — an Executive Summary, — an Explanatory Note, — a Regulatory Impact Assessment (RIA), — and the draft rule(s). <p>The RIA is a tool to support decision-making and is based on the Pre-RIA conducted at the programming phase (if a Pre-RIA was produced at that stage).</p>
Adopt NPA	Before publication, the NPA is circulated by the Processing and Proofreading assistant for adoption by ED, who can delegate to the relevant Director.
Launch the consultation of NPA	A public consultation for a period which varies from one to three months follows the publication of the NPA. In addition, during the consultation period, the Agency may, in exceptional and strictly justified cases, extend the consultation period at the request of Member State competent authorities or interested parties/stakeholders. This may happen, for instance, to allow MS/NAAs to translate the NPA.
Publish NPA	<p>Once adopted, the NPA is sent to EASA webmaster for publication on the Agency's website and a notification email is sent to IETC secretariat, RAG/TAGs/SSCC and FAA/TCCA (if applicable).</p> <p>Archiving is ensured according to the WI.IMS.00044 Archiving and filing of rulemaking deliverables.</p>

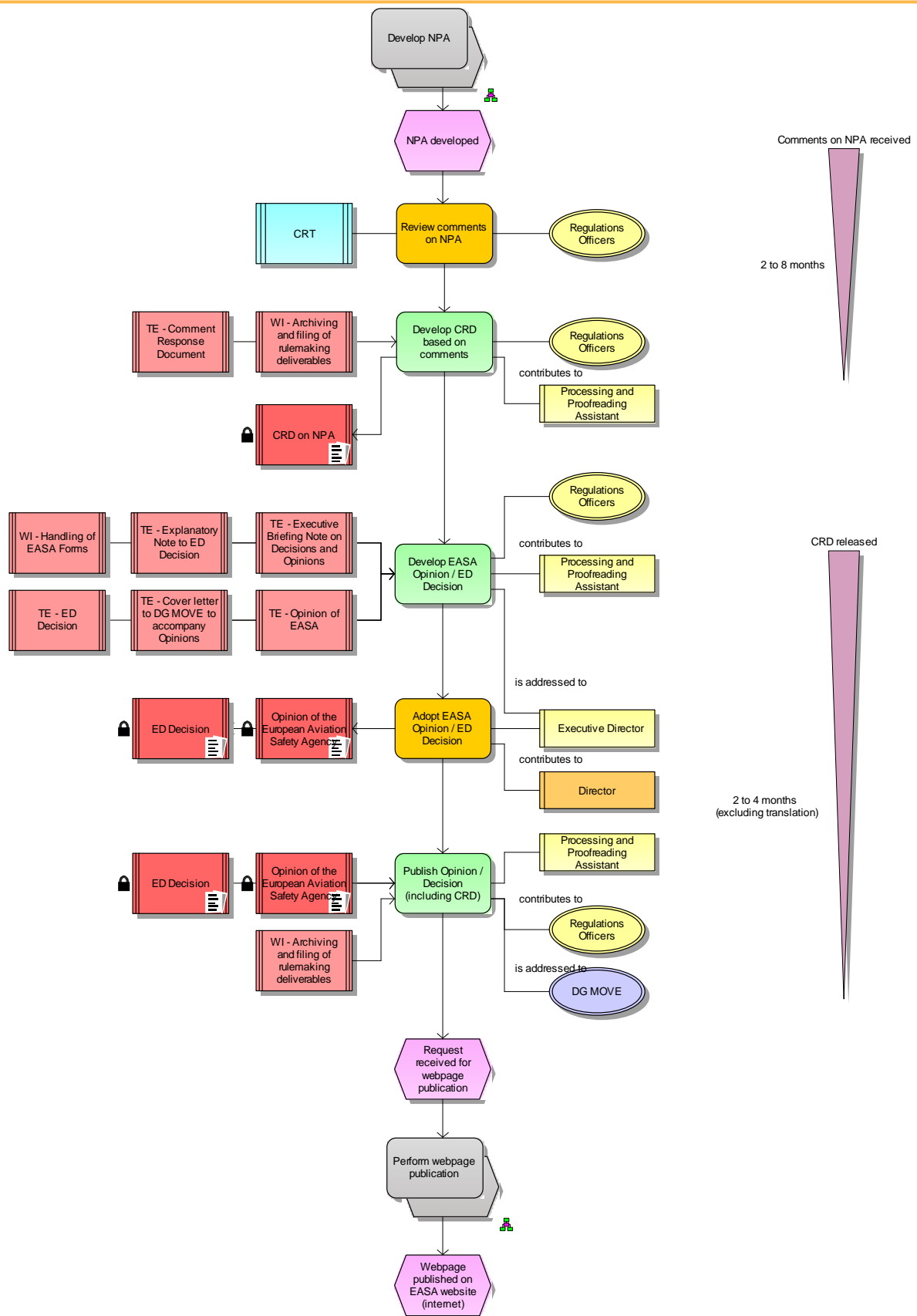
Internal Process Interfaces

Develop ToR
Develop Opinion, Decision
Perform webpage publication





Develop Opinion, Decision





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Activity	Description to the process activity
Review comments on NPA	<p>The Agency reviews the comments received and publishes a Comment-Response Document (CRD) as part of the final Opinion or Decision.</p> <p>The review of the comments received may be supported by a review group, which may consist of the original rulemaking group and/or involve external experts who have not directly participated in the drafting of the NPA.</p> <p>The review may also be supported by a form of focussed consultation (e.g. workshops, web-events, meeting with affected stakeholders).</p>
Develop CRD based on comments	<p>The CRD includes:</p> <ul style="list-style-type: none">- a summary of the comments received (and of the outcome of the focussed consultation, if any);- the Agency's responses thereto; and- a table of the individual comments received. <p>RO can also decide to provide responses to the individual comments.</p> <p>Archiving is ensured according to the WI.IMS.00044 Archiving and filing of rulemaking deliverables.</p>
Develop EASA Opinion / ED Decision	<p>Based on the outcome of the consultation and the review of comments, the following documents are produced in the development of an Opinion/Decision:</p> <ul style="list-style-type: none">- Explanatory Note (EN) to ED Decision;- draft Amending Regulation(s);- Executive Briefing Note on Decisions and Opinions (to shortly describe the issue and the outcome of the consultation to senior management). <p>The Opinion/Decision is issued together with the CRD. In addition, the Opinion is also accompanied by a cover letter to DG MOVE.</p>
Adopt EASA Opinion / ED Decision	<p>The final output of the rule development is the adoption by the ED. Before publication, the NPA is circulated by the Processing and Proofreading assistant for adoption by ED, who can delegate to the relevant Director, in case of:</p> <ul style="list-style-type: none">- an Opinion, which is submitted to the Commission for further processing; and/or- a ED Decision for CS, AMC or GM, which is then directly published and is immediately applicable.
Publish Opinion / Decision (including CRD)	<p>Decisions and Opinions issued by the Agency are published in the Agency's Official Publication and additionally on the Agency's website together with an Explanatory Note and, in the case of Opinions, with an updated RIA, if the final text differs significantly from the one that circulated at the beginning of the consultation process.</p> <p>For the Opinion, after the Agency has published an Opinion, the decision-making process is transferred to the European Commission (and thus is continued outside the Agency's mandate). A notification email is sent to IETC secretariat and to FAA/TCCA.</p> <p>Archiving is ensured according to the WI.IMS.00044 Archiving and filing of rulemaking deliverables.</p>





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Internal Process Interfaces

Develop NPA

Perform webpage publication





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RECORDS**Appendix A : Operational Documents**

Develop ToR	
Record	Activity
Rulemaking group composition	- Adopt ToR
Rulemaking Terms of Reference	- Adopt ToR

Develop NPA	
Record	Activity
Notice of Proposed Amendment (NPA)	- Adopt NPA

Develop Opinion, Decision	
Record	Activity
CRD on NPA	- Develop CRD based on comments
Opinion of the European Aviation Safety Agency	- Adopt EASA Opinion / ED Decision
ED Decision	- Adopt EASA Opinion / ED Decision

Appendix B : External Documents