Making the railway system
work better for society.

Procedure

Impact Assessment

	Drafted by	*Reviewed by*	*Approved by*
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Document History

Version	*Date*	*Comments*
1.0	31/01/2017	Updates after the Executive Board meeting (12/01/17).
2.0	25/02/2019	Minor changes due to the Agency reorganisation and IMS simplification.
3.0	19/01/2021	Update (including the flowchart) to align procedure with novel TSI transition regime and revised procedure for issuing Agency Opinions / Advices

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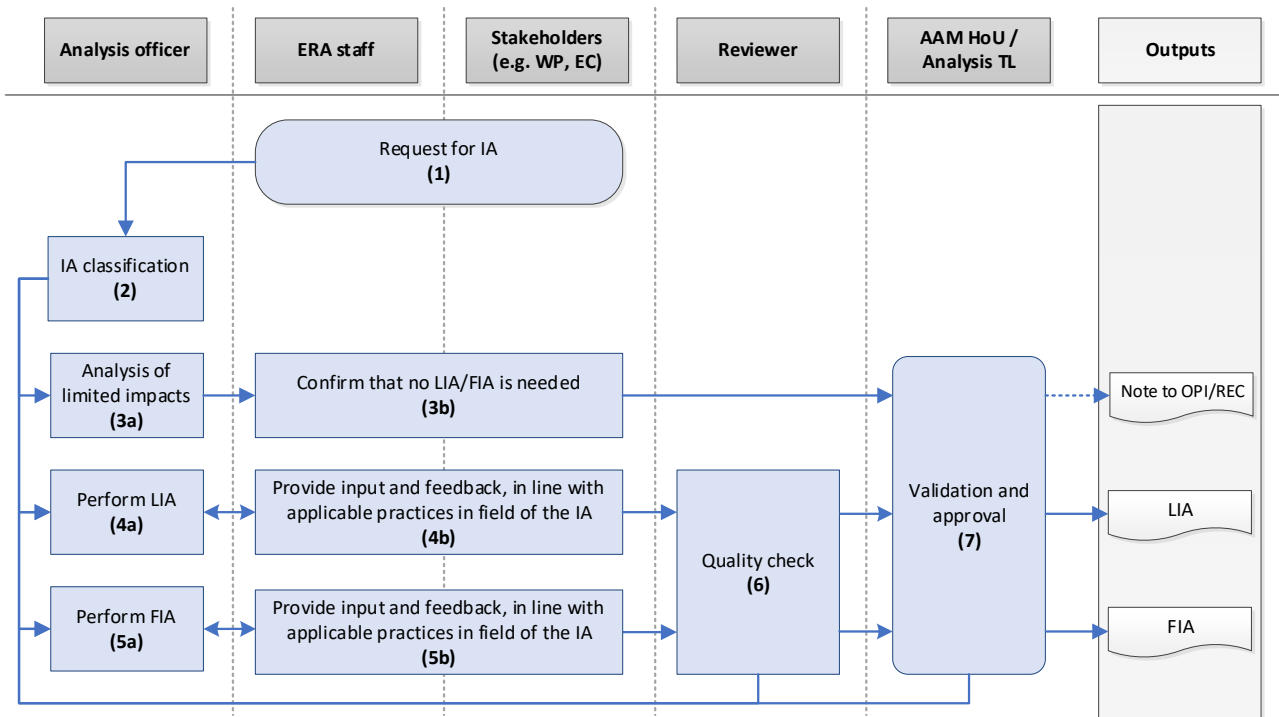|	
Process Deployment	Core processes > Developing > Ex-ante impact assessment (EEV)
Process Owner	Head of Analysis and Monitoring Unit
Purpose	To describe the steps and allocation of responsibilities for performing an impact assessment (IA).
Scope	The document applies to all the recommendations (REC) and opinions (OPI) of the European Union Agency for Railways (hereinafter called "the Agency").
	If other projects outside this scope require an impact assessment, this procedure may be applied with the necessary adaptations, as required.

Process Customers and other stakeholders	Various units/entities of the Agency
	Other stakeholders:
	› Agency's Management Team and Management Board
	› European Commission (EC)
	› Working Parties for REC and OPI, as appropriate
Process Input	› Change requests
	› Ad hoc requests for IAs from the Management Team, Management Board or EC
Process Output	Impact Assessment (Impact note, Light Impact Assessment or Full Impact Assessment)
Legal Basis	› Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways, Article 8(1)
	«The Agency shall conduct an impact assessment of its recommendations and opinions. The Management Board shall adopt an impact-assessment methodology based on the methodology of the Commission. The Agency shall liaise with the Commission to ensure that relevant work at the Commission is duly taken into account. The Agency shall clearly identify the assumptions used as the basis for the impact assessment and the data sources used in the report accompanying each recommendation.»
	› EC Better Regulation Guidelines 2021
Performance Indicators	› % of IAs which are timely delivered out of the total number of due IAs
Linked with other (Sub)Processes	› Core processes > Developing > Issuing an Agency's Recommendation (REC)
	› Core processes > Developing > Issuing an Agency's Opinion/Advice (OPI)
	› Core processes > Change Control Management (CCM)
	› Strategic processes > Strategic planning and reporting > Strategic Planning (STP)
Enablers	› Coaching on IA for project officers from operational units
	› Training on advanced evaluation methods for the project officers from the Analysis team

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	›	Coordination between the Agency and EC to define the IA cooperation cases and/or to clarify the ad hoc requests from the EC
	›	Railway System Data Inventory (RSDi)

Process Constraints	›	Extent to which stakeholder groups provide input data for the IA
	›	Possible short time frames for delivering IAs, especially in the case of OPI
	›	Complexity to evaluate the costs and benefits of CRs in terms of absolute numbers and how stakeholder groups are affected
Related Documents	›	PRO_OPI_001 Issuing an Agency's Opinion - Advice
	›	PRO_REC_001 Issuing an Agency's Recommendation
	›	PRO_CCM_002 Change Control Management
	›	RUL_DOM_002 DMS Rules

1. Definitions and Abbreviations

See 'Glossary' for acronyms and definitions.

2. Flow Chart

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3. Description

3.1. Step 1. Request for IA

An IA is legally mandated for all the Agency's Opinions and Recommendations. Additionally, an IA can be performed as part of a decision-making process with high relevance for the Agency (e.g. Agency's SPD objectives and/or individual project, etc.) and for Advices.

The Agency IAs are distinct and independent from the IAs conducted by the European Commission.

The IA is led by the Analysis Officer(s) allocated to the project, based on input from the involved ERA Staff and stakeholders, notably the Working Party and the EC. Input from the involved stakeholders is taken into account via the relevant groups and channels from the very early stages of the IA process.

From an IA perspective there are six main fields:

› Rolling Stock TSIs (LOC&PAS/WAG/NOI/PRM)
› CCS TSI
› TAP and TAF TSI
› OPE and Fixed Installation TSIs
› CSMs
› Others (Registers, Agency activities, etc.)

Change control management application processes in a certain field can stipulate particular IA requirements. Acknowledging these specificities, this document describes the processes that apply across all fields.

3.2. Step 2. IA Classification

An IA has different purposes, such as being an explanatory, exploratory, or a decision support document. In first instance, the Analysis Officer and requestor(s) define the scope and depth of an IA and agree on the appropriate output document collectively.

Three distinct IA outputs are possible:

› **An impact note** is a concise analysis that is added to a Recommendation or Opinion in case the expected impacts are negligible or previously adequately assessed. The required content of an impact note is described under section 3.3.
› **A light impact assessment** (LIA) provides a mostly qualitative analysis of the main impacts of a change using the IA template (**TEM_EEV_001**).
› **A full impact assessment** (FIA) provides a qualitative and quantitative analyses of the impacts of a change using the IA template (**TEM_EEV_001**).

All three outputs shall be acceptable means to comply with Agency Regulation Art 8(1).

Without prejudice to existing field specific processes, the table below provides guidelines on what type of change is associated with which kind of output.

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Table 1. IA output guidelines

Field / Output	RST	CCS	TAP / TAF	OPE / FI	CSMs	Others
Impact note	C1 changes[1]	C1 changes[1]	Error corrections			
Light IA	C2 changes[2]	C2 changes[2]	Low impact enhancements	*Output to be defined according to the specific request*		
Full IA	C3 changes[3]	C3 changes[3]	High impact enhancements			

The outputs that are associated with the different types of changes as shown in the table above are indicative, and the involved parties can jointly decide on the most appropriate output document.

3.3. Step 3a. Analysis of limited impacts

The Analysis Officer determines whether the considered changes will have negligible impacts on any stakeholder group, or if the impacts were already adequately assessed in a previous Agency IA.

Such can be the case if:

› a TSI requirement becomes less strict, providing more flexibility to the railway sector, or if
› An Opinion or Recommendation, and thus an IA, addresses an issue in an existing piece of legislation, but there are no additional or evolving impacts identified compared to those that were assessed in an ERA IA when that legislation was initially scrutinised.

In such cases the Analysis Officer can opt for an impact note that will be added to an Opinion or Recommendation.

An impact note contains at least the following points:

› The reasoning why the impacts are very likely to be negligible on the short and long term for various stakeholder groups, and/or
› The reference to and description of the impacts in a prior Agency IA, together with an explanation on why the impacts have been adequately assessed already.

The Analysis Officer will draft a LIA instead of an impact note in case the group responsible for evaluating the change explicitly requests a LIA.

3.4. Step 3b. Confirm analysis

The Analysis Officer shall share its findings with the involved ERA Staff and stakeholders, including the reasoning why no LIA or FIA is needed. If no new arguments are presented why a LIA or FIA would be needed, the impact note will be shared with the AAM HoU and/or Analysis TL for validation (Step 7).

3.5. Step 4a. Perform LIA

The LIA is led by the Analysis Officer(s) allocated to the project, using input from the involved ERA Staff and stakeholders.

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[1] *concerns a TSI clause or requirement for which the conformity with the previous version of that TSI ensures in all cases the conformity with the new version*

[2] *concerns a TSI clause or requirement for which conformity with the previous version of that TSI does not lead to conformity with the new version. For changes of category C2, a generic transition regime from a version of a TSI to the next version is defined in each TSI.*

[3] *a TSI clause or requirement for which the conformity with the previous version of that TSI does not ensure the conformity with the new version and for which a specific transition regime is defined in order to promote a swift implementation.*

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The LIA is drafted using the Impact Assessment template (TEM_EEV_001), which includes the guiding methodological questions.

In case when multiple options cannot be identified, only the relevant parts of the template will be filled, demonstrating that no alternative options could be analysed and drawing the conclusions based on a proportionate analysis.

3.6.   Step 4b. LIA: Interaction with ERA staff and stakeholders

The draft of the LIA is shared with stakeholders via the involved working party or other relevant fora (e.g. NSA network, NRB, RISC, EC, ERA management) to enable stakeholders to provide their feedback on the content of the LIA. The Analysis Officer considers the feedback when revising the document. The involved ERA staff or stakeholders may also provide or request further evidence, which could occur in the case of complex and/or controversial projects with diverging views among various stakeholders.

In case several of the involved stakeholders call for a deeper analysis through a FIA, and if the underlying reasons for this request are considered justified by the Analysis Officer, the AAM HoU or the Analysis Team leader is asked to approve the change from a LIA to a FIA.

If no further evidence is needed, the draft of the LIA enters Step 6.

3.7.   Step 5a. Perform FIA

The FIA is led by the Analysis Officer(s) allocated to the project, using input from the involved ERA staff and stakeholders. The FIA draws on qualitative inputs and aims for the quantification of impacts to the greatest possible extent.

The FIA is drafted using the Impact Assessment template (TEM_EEV_001), which includes the guiding methodological questions. The data from the Agency's Railway System Data Inventory (RSDI) will be used for the quantification of impacts. Where such values do not exist in the RSDI, they can be retrieved through other data collection efforts and the collected data shall subsequently be fed back into the RSDI.

3.8.   Step 5b. FIA: Interaction with ERA staff and stakeholders

The draft of the FIA is shared with stakeholders via the involved working party or other relevant fora (e.g. NSA network, NRB, RISC, EC, ERA management) to enable stakeholders to provide their feedback on the content of the FIA. The Analysis Officer considers the feedback when revising the document. The involved ERA staff or stakeholders may also provide or request further evidence, which could occur in the case of complex and/or controversial projects with diverging views among various stakeholders.

If no further evidence is needed, the draft of the FIA enters Step 6.

3.9.   Step 6. Quality check

The Reviewer is normally an Analysis Officer who was not directly involved in the IA. The Reviewer analyses the suitability and quality of the methodologies applied and data used. Depending on the availability of time, the Reviewer can already be involved in the drafting phase of the IA to ensure an ongoing quality check.

The Analysis Officer implements the conclusions of the quality check, if any, after which the LIA or FIA proceeds to Step 7.

3.10.   Step 7. Validation and approval

The final version of the document reflects the retained feedback from ERA Staff, external stakeholders and the feedback from the reviewer.

In case an impact note, LIA or FIA is drafted for a REC or OPI, the Head of AAM and/or the Analysis TL shall perform the final review and, if positive, approves the IA (see PRO_REC_001 and PRO_OPI_001). In case an

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impact note, LIA or FIA is not drafted for a REC/OPI, the Analysis TL shall perform the final review and, if positive, approve the IA. The IA report shall be stored according to the DMS rules (RUL_DOM_002).

4. Standard workload per step

On average, it is expected that:

› an **Impact Note** would require approx. 2 person-days of work by the Analysis Officers and 1 person-day of work by the project officer(s) from the operational units;
› a **LIA** would require approx. 15 person-days of work by the Analysis Officers and 5 person-days of work by the project officer(s) from the operational units;
› a **FIA** would require approx. 60 person-days of work by the Analysis Officers and 10 person-days of work by the project officer(s) from the operational units.

These values may, on a general basis, be taken into account for the MS Project planning. They may be subject to adaptation in specific cases, which deviate from the average.

5. Templates / Forms

› TEM_EEV_001 (IA template for LIA and FIA. Impact Notes include the elements described under section 3.3 but do not follow a specific template)
› TEM_EEV_002 (Slides for presentation to RISC)

6. Records and Other Outputs

Record Name	Storage Responsible	Storage Location	Minimum Retention Time
IA report (Note, LIA or FIA)	Opinion Responsible and where applicable Analysis Officer in charge	Intranet: Register for Opinions/ Recommendations, Impact Assessment library; Extranet space: (in case of projects resulting in a recommendation) ERA website: recommendations and opinions	The same retention time as for the REC and OPI documents according to the related procedures