

**Guidance for safety  
certification and  
supervision**



# **Application guide for the granting of single safety certificates**

## **A guide for the authorities**

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**Guidance for safety certification and supervision**

# **Application guide for the granting of single safety certificates**

**A guide for the authorities**

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# 1. Introduction

Railway undertakings and infrastructure managers bear the full responsibility for the safe operation of the railway system and the control of risks associated with it, each in relation to its own part of the system. The establishment of a safety management system is identified as the appropriate way to fulfil this responsibility.

The single safety certificate gives evidence that the railway undertaking has established its safety management system and is able to comply with the legal obligations as referred to in Article 10(3) of Directive (EU) 2016/798.

Access to the railway infrastructure should be granted only to railway undertakings that hold a valid single safety certificate.

The single safety certificate is valid for a given area of operation, i.e. a network or networks within one or more Member States where the railway undertaking intends to operate.

Depending on the area of operation, the issuing authority (also named hereafter 'the safety certification body') can be either the European Union Agency for Railways (also named hereafter 'the Agency') or the competent national safety authority. For ease of reading and unless stated otherwise, the case where the Agency is responsible for issuing the single safety certificates is used as a basis for the guidance in this document. This includes collaboration with one or more national safety authorities dependent on the area of operation. However, the same guidelines apply in the case where the application for a single safety certificate is addressed to a national safety authority.

This guidance document is a living document, which has been developed in collaboration with national safety authorities and sector representatives, and is intended to be continually improved based on the feedback of users and taking into account the experience gained during the implementation of Directive (EU) 2016/798 and relevant Union law.

Templates and forms referred to in the present document are available in the one-stop shop.

## 1.1. Purpose of the guide

This guidance document is aimed at assisting the authorities responsible for the safety assessment in relation to issuing the single safety certificate.

In addition, it details the safety assessment from the perspective of the authority.

This document also provides model templates for forms that can be used by the Agency and national safety authorities during the safety assessment process.

## 1.2. Who is this guide for?

This document is addressed to the Agency and national safety authorities when undertaking the safety assessment in relation to taking a decision over the issue of single safety certificates.

### 1.3. Scope

This document provides detailed practical information that is primarily intended to support authorities involved in the safety assessment process in understanding the requirements regarding single safety certificates, as stipulated in the European legal framework. This guide is supplemented by:

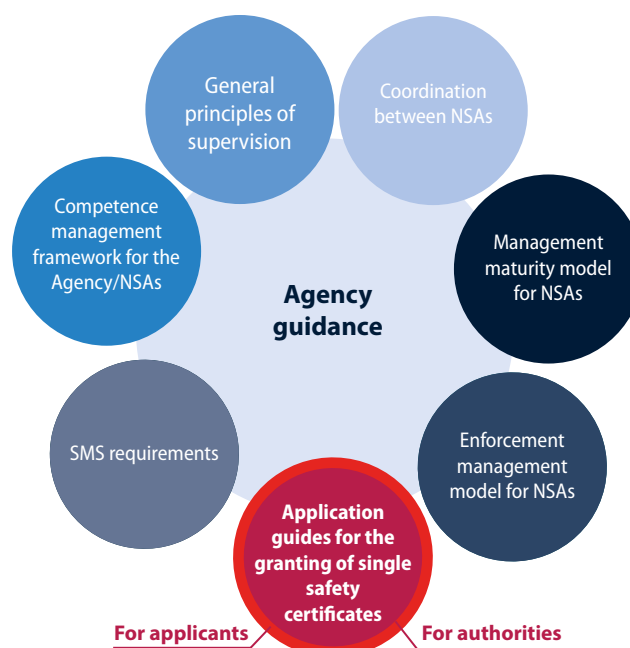
- ▶ The Agency application guide for the granting of single safety certificates – A guide for the applicants;
- ▶ The application guide of the national safety authority describing and explaining the national procedural rules, including the documents to be submitted by the applicant to demonstrate compliance with the national rules, the applicable language policy of the national safety authority (or the Member State) and further information about appeals against the national safety authority decisions (see also [Annex 1](#)).

It does not seek to duplicate the above guidance but rather to explain the details of the safety assessment, which are of general interest for the authorities involved in the process.

### 1.4. Guidance structure

This document is one of the two guides that the Agency has published covering the granting of a single safety certificate, the other being the application guide for applicants. It is also part of the Agency compendium of guidance supporting railway undertakings, infrastructure managers, national safety authorities and the Agency, in fulfilling their roles and undertaking their tasks in accordance with Directive (EU) 2016/798. The information published in this guide is supplemented by other guidance to be developed by the national safety authorities, as mentioned above.

Figure 1: Compendium of Agency guidance



## 1.5. European legal framework

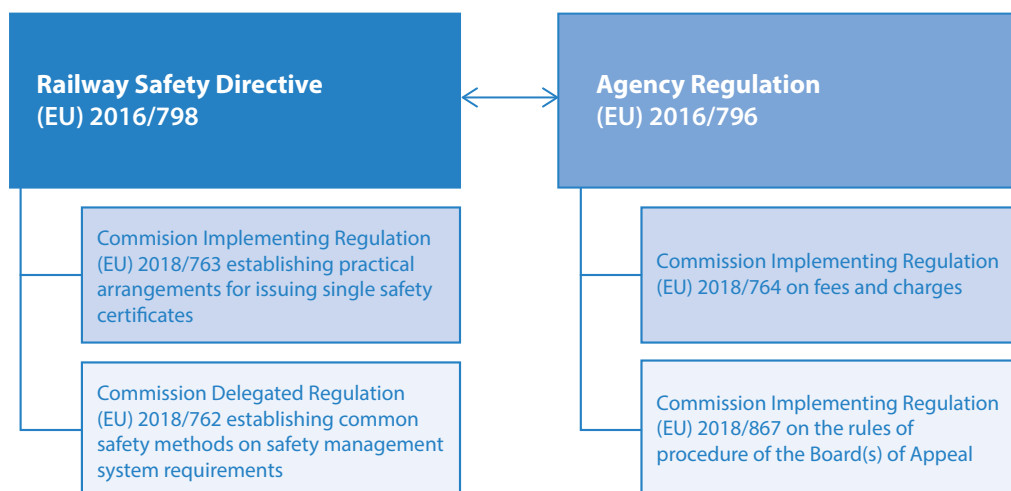
**Directive (EU) 2016/798 on railway safety (Railway Safety Directive)** is one of the three legislative acts that form the technical pillar of the 4th Railway Package. It aims at the simplification and harmonisation of the safety assessment process to benefit the applicants who apply for a single safety certificate. This will help to reduce the burden and costs being borne by the applicants, irrespective of the intended area of operation and of the authority responsible for issuing the single safety certificate.

In accordance with Directive (EU) 2016/798, the purpose of the single safety certificate is to provide evidence that the railway undertaking:

- ▶ Has established its safety management system as stipulated in Article 9 of Directive (EU) 2016/798;
- ▶ Meets the requirements laid down in the relevant notified national rules; and
- ▶ Is able to operate safely.

The European legal framework relevant for the granting of single safety certificates is summarised in Figure 2 below.

Figure 2: Overview of the European legal framework



**Regulation (EU) 2016/796 on the European Railway Agency for Railways (Agency Regulation)**, being one of the other two legislative acts of the technical pillar of the 4th Railway Package, describes, among other things, the role and responsibilities of the Agency in relation to the granting of single safety certificates.

**Commission Implementing Regulation (EU) 2018/763** establishing practical arrangements for issuing single safety certificates further increases harmonisation of the approach to safety certification at Union level and fosters collaboration among all the parties involved in the safety assessment process. It therefore clarifies the responsibilities of the Agency, the national safety authorities and the applicant and sets out the provisions necessary for smooth cooperation between them. Annex II of this Regulation provides a structured and auditable

process that ensures that the competent authorities (i.e. the Agency and the national safety authorities) take similar decisions in similar circumstances and that there is a degree of assurance that the assessment process is undertaken in a similar way by all authorities.

**Commission Delegated Regulation (EU) 2018/762** establishing common safety methods on safety management system requirements (also named hereafter ‘the CSMs on SMS’) provides in its Annex I the requirements to be evaluated by the competent authorities to assess the relevance, consistency and adequacy of the railway undertaking’s SMS. In addition, the applicant for the single safety certificate has to provide evidence in its application file that it complies with these requirements.

**Commission Implementing Regulation (EU) 2018/764** lays down the fees and charges payable to the Agency and their conditions of payment, in particular:

- ▶ Fees and charges levied by the Agency for applications addressed to the Agency, including the costs for tasks assigned to the national safety authority; and
- ▶ Charges for services offered by the Agency.

Fees and charges levied by the national safety authority for domestic applications addressed to it are outside the scope of the above Regulation and therefore, are regulated at national level.

**Commission Implementing Regulation (EU) 2018/867** lays down the rules of procedure of the Board(s) of Appeal of the Agency. These Rules describe namely the procedure applied during an appeal or arbitration case relating to the Agency issuing the single safety certificate. They provide details on the lodging of an appeal, the Board(s) of Appeal’s workings and voting rules, the conditions for reimbursement of expenses of their members, etc.



## 2. The safety assessment

### 2.1. The one-stop shop

In order to take part in the safety assessment of an application for a single safety certificate, the staff of the authority must be registered users of the one-stop shop. They must be assigned to the application by the programme manager of their respective authorities after being notified of a new application involving them. By definition, a user is a natural person appointed by the authority to manage the safety assessment in the one-stop shop. The management of users within the authority's organisation (e.g. in case of sick leave) and related access rights to applications is the sole responsibility of the relevant authority and its programme manager.

The one-stop shop is designed with the aim of recording the results and outcome of the assessment process, including the reasons for it. It also provides the applicant with the status of all stages of the safety assessment process, the outcome of the assessment and the decision whether or not to issue a single safety certificate. The applicant can scrutinise the results and outcome of the assessment once the latter is approved by the relevant authority. When several authorities are involved in the safety assessment the results and outcome of the assessment of the different authorities are compiled by the Agency. The decision whether or not to issue the single safety certificate and the reasons for it are then notified to the applicant through the one-stop shop. Similarly, when the Agency is the safety certification body, the notification of invoicing is managed through the one-stop shop.

The one-stop shop also ensures configuration management of all uploaded documents. The staff of the authorities involved in the safety assessment have the necessary credentials to access all documents and information relating to an application to which they are assigned (i.e. the application file as well as other documents or information pertaining to the assessment). The staff of an authority have read-only access to the results and outcome of the assessment of another authority. Similarly to the applicant, the authority's staff can also submit new or revised documents during the course of the assessment to support its decision. Documents recorded in the system cannot be deleted but can only be replaced by a newer version or marked as obsolete.

Any applicant has the right to prepare and submit at any time valid applications in the one-stop shop in line with the applicable EU railway legislation, the specifications and the Terms of Use of the one-stop shop. When the Agency acts as safety certification body, the application for a single safety certificate is submitted to the Agency which has to refer the application file to the national safety authority or authorities concerned with the area of operation to address the national rules part, (this is done automatically via the one stop shop).

In such cases, the compliance with any formal and substantial rules, requirements, prerequisites or conditions linked with administrative issues, such as:

- ▶ finalisation and formal submission of an application in the one-stop shop;
- ▶ content of formal acknowledgement of receipt of an application by the Agency;
- ▶ requirement of signature of applications in the one-stop shop and Agency's reports, including final decisions/acts; and
- ▶ any other relevant EU law governed issue.

falls under the exclusive responsibility of the Agency which defines the relevant specifications. Consequently, in relation to the aforementioned administrative issues, all national safety authorities involved in the assessment of an application (when the Agency acts as safety certification body) should consider any application submitted in the one-stop shop as valid, given also that when the Agency acts as safety certification body it is subject to EU law and not to any national requirements set out in the national administrative law of the EU Member States.

## 2. The safety assessment

The key features of the one-stop shop are summarised in the following table:

**Table 1:** One-stop shop key features

<b>Applicant</b>	<b>Authorities involved in the safety assessment</b>
▶ Submission of an electronic application file;	▶ Acknowledgement of receipt of an application;
▶ Configuration management of the application file ( <i>library</i> );	▶ Configuration management of the assessment file ( <i>library</i> );
▶ Viewing of milestones and progress status of the different stages of the safety assessment process ( <i>dashboard</i> );	▶ Setting of milestones and reporting on progress against the different stages of the safety assessment process ( <i>dashboard</i> );
▶ Recording of communications with the authorities ( <i>issue log</i> ), ensuring a traceability of decisions;	▶ Recording of communications with the applicant ( <i>issue log</i> ), ensuring traceability of decisions;
▶ Viewing the assessment results and outcome (once approved);	▶ Reporting the assessment results and outcome;
▶ Notification of the decision relating to the issue of the single safety certificate;	▶ Communicating the decision relating to the issue of the single safety certificate;
▶ Management of requests for the review of the decisions of the safety certification body;	▶ Authentication and management of users;
▶ Authentication and management of users;	▶ Assignment of users to the application (roles and rights management);
▶ Assignment of users to the application;	▶ Management of all applications for a single safety certificate assigned to the authority;
▶ Management of all applications for a single safety certificate submitted by the applicant;	▶ Recording of events ( <i>event log</i> );
▶ Recording of events ( <i>event log</i> ).	▶ Update of ERADIS database.

The national safety authority is free to establish its own information management system on the condition that any issues addressed to the applicant are communicated through the one-stop shop. This includes any documents necessary to ensure that the traceability of decisions is transferred to the one-stop shop before the decision making process takes place.

More information regarding the one-stop shop functionalities can be found in the *one-stop shop user manual*.

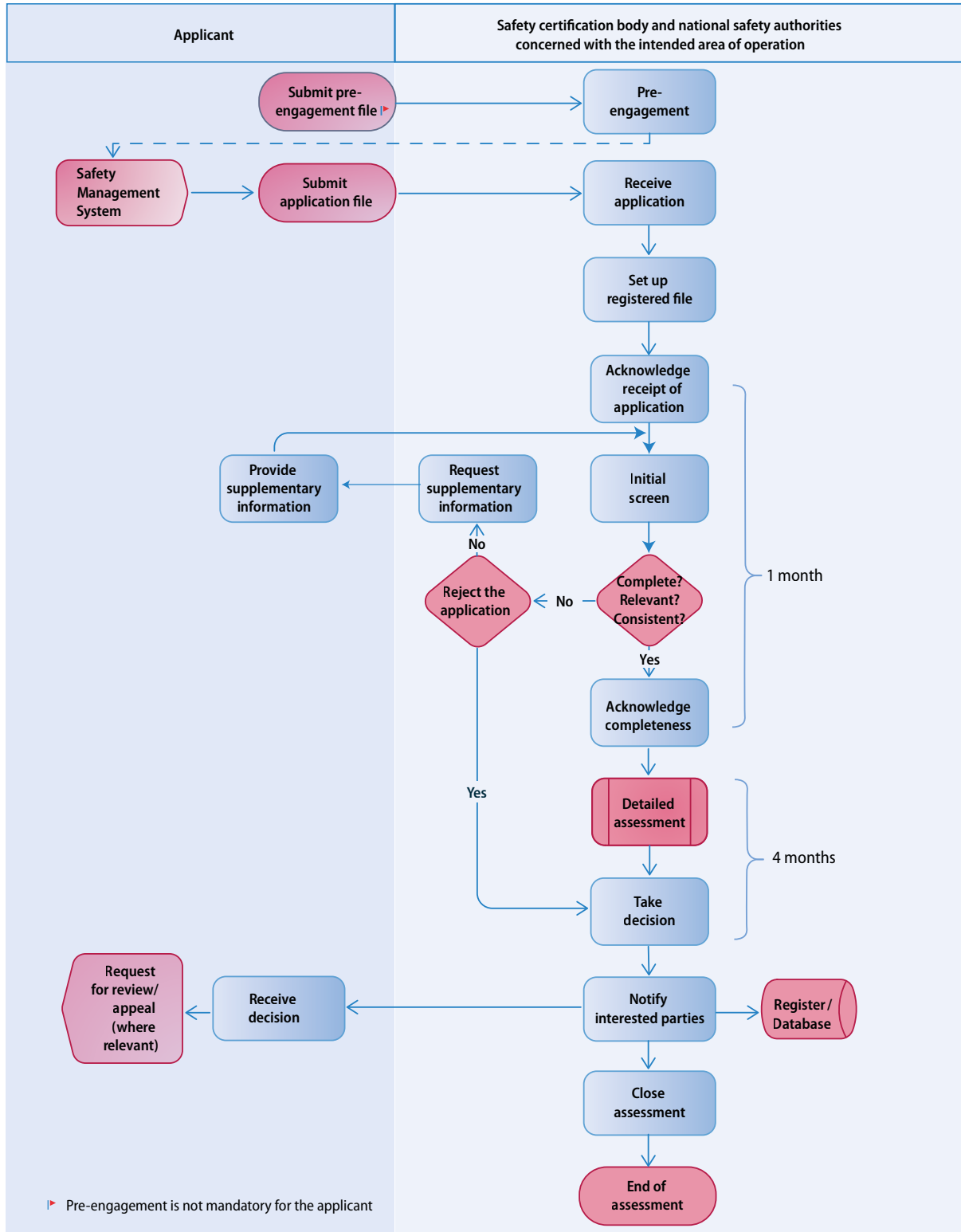
### 2.2. Safety assessment process

The safety assessment process is defined in Annex II of Commission Implementing Regulation (EU) 2018/763 and contains the following stages, as shown in Figure 3: The safety assessment process.:

- ▶ Pre-engagement (optional);
- ▶ Receipt of application;
- ▶ Initial screen;
- ▶ Detailed assessment;
- ▶ Decision-making;
- ▶ Closing of the assessment.

In the following sections, the safety assessment process is detailed from the authorities' perspective.

**Figure 3:** The safety assessment process.



### 2.2.1. Pre-engagement

To make pre-engagement effective in achieving its full benefits, the following approach is advocated:

- ▶ The applicant prepares a file which includes at least an overview of its SMS and submits it through the one-stop shop. The file must include the information listed in items 1-6 of Annex 1 of Commission Implementing Regulation 2018/763 (EU) but the amount of information provided is not limited to this list;
- ▶ The safety certification body sets the date(s) of the meeting(s) and is responsible for the organisational arrangements (e.g. meeting venue or use of other communication means, invitation of experts);
- ▶ The applicant sets the agenda of the meeting(s);
- ▶ The national safety authority for the area of operation provides overall results/trends from their previous supervision as applicable, on the request of the safety certification body;
- ▶ The safety certification body coordinates with the applicant and other national safety authorities as appropriate, with the aim of discussing the content of the pre-engagement file and, if considered to be relevant for the application, the feedback from supervision activities performed by the relevant national safety authority (or authorities);
- ▶ For the sake of transparency and the clarity of exchanges between the Agency (when acting as safety certification body), relevant national safety authority (or authorities) and the applicant, issues identified at the pre-engagement stage are recorded and tracked following the same principles used for the assessment itself (see sections 2.2.3 and 2.2.4). The same approach is also strongly recommended if the safety certification body is a national safety authority;
- ▶ The applicant keeps records of the meeting(s) by drafting and circulating the minutes for review and approval by all participants. The records of the meeting(s) can be archived in the one-stop shop to facilitate the future safety assessment.

### 2.2.2. Receipt of the application

Following the submission of an application for a single safety certificate (new, update or renewal), the one-stop-shop automatically and immediately acknowledges the receipt of the application on behalf of the safety certification body. It should be noted that all first applications for a single safety certificate whether the applicant has held a previous safety certificate or not, should be entered in the one-stop shop as 'new' applications. If the applicant has held a previous safety certificate under the previous regime this may be taken into account by the safety certification body in carrying out its assessment of the file. To make this process more efficient applicants should indicate in their application any changes made to their safety management system since the last assessment. The notification sent to the applicant also includes information about the start date of the assessment against which milestones and deadlines will be monitored. The start date of the assessment corresponds to the date of acknowledgement of receipt of the application as defined in Article 2(2) of Commission Implementing Regulation (EU) 2018/763 (practical arrangements for issuing single safety certificates to railway undertakings).



The receipt of an application is not acknowledged by the authorities for the intended area of operation, but only by the safety certification body. As all communication on new applications will be addressed to appointed programme managers, to avoid problems such as the individual's absence when a new application is submitted, the authorities are encouraged to set up an additional functional mailbox to which all notifications are forwarded.



To support the notification process, the Agency and the national safety authorities are invited to use the one-stop shop to record information about public holidays applicable to their organisation. This information is used by the one-stop-shop to process the start date of the assessment which is set in the acknowledgement of receipt of the application. The information on public holidays for a given year is recorded in the system by each of the authorities not later than the end of the preceding year and is updated, if necessary, when there are changes in public holidays within the year.

For each application, the competent resources are assigned within the one-stop shop by the programme manager of each authority concerned with the area of operation. To avoid shortening the time available for the safety assessment, the authorities concerned are invited to assign their resources promptly (see section 2.3).

The following table describes the various roles and responsibilities available in the one-stop shop for the different authorities (i.e. the Agency and national safety authorities). According to the complexity of the application and its internal procedure, each authority allocates one or more resources to conclude the safety assessment process within the legal timeframe. The same resource can be assigned one or more roles. Each application is managed as a project with a specific start and end date corresponding respectively to the acknowledgement of receipt of the application and the decision taken by the safety certification body. It is recommended that the project management methodology is proportionate to the size and complexity of the application.

Table 2: Roles and responsibilities

Roles	Responsibilities
Programme Manager	Responsible for the set-up, management and delivery of the programme, which entails: <ul style="list-style-type: none"> <li>▶ Receiving notifications of new applications;</li> <li>▶ Forward planning resources to address new, update and renewal applications;</li> <li>▶ Assigning competent resources to each project;</li> <li>▶ Ensuring consistency of the decisions made for the different projects;</li> <li>▶ Managing the evaluation of the effectiveness of the programme and its continual improvement.</li> </ul>
Project Manager	Responsible for the set-up, management and delivery of the safety certification project assigned to him/her, which entails: <ul style="list-style-type: none"> <li>▶ Providing leadership and coordinating the assessment process, including pre- engagement as applicable;</li> <li>▶ Fulfilling the project objectives, in particular the timely delivery of the assessment work in accordance with quality standards;</li> <li>▶ Identifying any issues that could prevent the completion of the assessment;</li> <li>▶ Liaising with the programme manager to share issues that may affect the completion of the assessment and the final decision-making over whether or not to issue the single safety certificate;</li> <li>▶ Escalating any diverging opinions between assessors that could not be resolved by the decision-maker(s);</li> </ul>

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- ▶ Suspending the assessment whenever a significant issue is identified, pending the receipt of supplementary information from the applicant;
- ▶ Managing the recommendation whether to issue the single safety certificate;
- ▶ Submitting any rejection decision at an early stage of the process (i.e. before the completion of the assessment) to the decision-maker(s);
- ▶ Reporting on the progress of the assessment to the decision-maker(s);
- ▶ Preparing the single safety certificate (if the decision is to issue the single safety certificate);
- ▶ Ensuring the correct application of the relevant processes and procedures.

Lead Assessor (if more than one assessor)	Responsible for the set-up, management and delivery of the technical assessment of a safety certification project assigned to him/her, which entails: <ul style="list-style-type: none"> <li>▶ Coordinating the technical work between assessors as appropriate at different stages of the assessment process and during pre- engagement as applicable;</li> <li>▶ Liaising with the project manager to share issues that may impede the completion of the assessment;</li> <li>▶ Escalating any diverging opinions between assessors that cannot be resolved to the project manager;</li> <li>▶ Ensuring consistency of the decisions among the different assessors;</li> <li>▶ Managing the overall results of the assessment.</li> </ul> In addition, the responsibilities set out below for the assessor apply.
Assessor	Responsible for the specific part(s) of the assessment assigned to him/her, which entails: <ul style="list-style-type: none"> <li>▶ Contributing to fulfil the project objectives, in particular the timely delivery of the assessment work in accordance with quality standards;</li> <li>▶ Coordinating with the applicant as appropriate, e.g. to request supplementary information or clarification or to agree on action plan(s) set by the applicant;</li> <li>▶ Identifying any issues that could prevent the completion of the assessment;</li> <li>▶ Liaising with the lead assessor to share issues that may impede its part(s) of the assessment or that of another assessor(s);</li> <li>▶ Managing the results of its part(s) of the assessment;</li> <li>▶ Reporting on the progress of its part(s) of the assessment to the lead assessor and project manager (if different from the lead assessor);</li> <li>▶ Applying the relevant processes and procedures.</li> </ul>
Assuror	Responsible for checking that the safety assessment process has been correctly applied before making any decision over whether to issue of the single safety certificate, which entails: <ul style="list-style-type: none"> <li>▶ Checking the correct application of the relevant processes and procedures;</li> <li>▶ Providing a recommendation whether to issue the single safety certificate, including any rejection decision at an early stage of the process (i.e. before the completion of the assessment), based on the results of its checks;</li> <li>▶ Submitting its recommendation to the decision-maker(s).</li> </ul>
Decision-maker	Responsible for approving the opinion and/or taking the decision over whether to issue the single safety certificate.

### 2.2.3. Initial screen

Where the Agency acts as safety certification body, coordination is to be sought between authorities involved in the safety assessment in order to discuss:

- ▶ The internal and external communication (see section 2.4);
- ▶ The organisational arrangements;
- ▶ The task assignment;
- ▶ The detailed schedule;
- ▶ Relevant Information collected on the applicant's safety performance from past supervision activities as applicable (see also section 2.7). This information is provided by the national safety authority;
- ▶ Feedback from pre-engagement as applicable.

Preferably, a first coordination meeting is held shortly after the various resources are assigned to the application. Other coordination meetings can be arranged at the request of the safety certification body to discuss intermediate and final results of the initial screen.

Where the applicant indicates in its application that it intends to operate to stations in neighbouring Member States with similar network characteristics and similar operating rules when those stations are close to the border, the safety certification body should consult the competent national safety authority (or authorities) of the relevant neighbouring Member States. These national safety authorities should confirm that they agree to the national safety authorities for the intended area of operation checking that the relevant notified national rules and the obligation arising from the relevant cross-border agreements are met. The conclusions of this consultation will be provided by the safety certification body in the assessment report. If the case is that an arrangement that allows the national safety authority involved in the safety assessment to work on behalf of the national safety authority of the neighbouring Member State cannot be reached, the applicant will be asked to amend its application for a single safety certificate to include in its intended area of operation the network of the Member State in question.

The above-mentioned consultation does not have to take place if specific cross-border agreements exist between Member States or national safety authorities that cater for operations between stations close to the border where there are similar network characteristics and similar operating rules. In such cases, the national safety authorities for the intended area of operation are considered to be competent to check that the relevant notified national rules and the obligations arising from the relevant cross-border agreements are met. The national safety authorities are invited to identify these cooperation arrangements and the border stations covered by them in their national application guide (see [Annex 1](#)) to facilitate the assessment process.



The authorities and the applicants may use different communication channels at their discretion to make the assessment more efficient. However, the identification and recording of issues (in the meaning of Article 12 of Regulation (EU) 2018/763) should be managed through the issue log of the one-stop shop in order to ensure transparency and traceability of the decisions taken by the authorities concerned with the area of operation.



There are 4 types of issues that can be raised via the issue log in the one-stop shop. These range from a request for further information (a 'Type 1' issue), a matter that the authority wishes the applicant to correct but which can be left to their discretion to manage, (a 'Type 2' issue), a minor non-compliance or a residual concern which will be transferred by the authority for examination under later supervision, (a 'Type 3' issue) and a matter which is a blocking point for the application, (a 'Type 4' issue). Further details and examples of each of these types of issues can be found in the Agency application guide for granting single safety certificates – A guide for the applicants.

As part of their request for more information, each authority can seek as much detailed information as it deems reasonably necessary to help its assessment of the application and to that end can make direct contact with the applicant. When doing so each authority is requested to be precise and accurate, and to provide clear and understandable information to the applicant together with a timeframe for the expected response. In turn, the applicant provides the requested information within the agreed timeframe through the issue log.



## 2. The safety assessment

If the applicant does not provide the requested information or if the supplementary information provided in the application is not satisfactory, the timeframe of the assessment may be extended or an application can be rejected. Rejecting an application is used as the last resort and when the safety certification body decides to do so the decision and the reasons for it are recorded in the assessment report and notified to the applicant. Any rejection decision requires a resubmission of the application.

As the authorities involved in the safety assessment can be consulted on the content of the application before its submission (i.e. during a pre-engagement stage), they may already know that the application contains adequate evidence, in which case it will be possible to reduce this stage to a minimum as appropriate and move faster on to the main assessment. It may also be that the results from previous supervision activities provide sufficient knowledge of the applicant so that a decision on the application can be made. In such cases, a justification needs to be recorded in the assessment report.

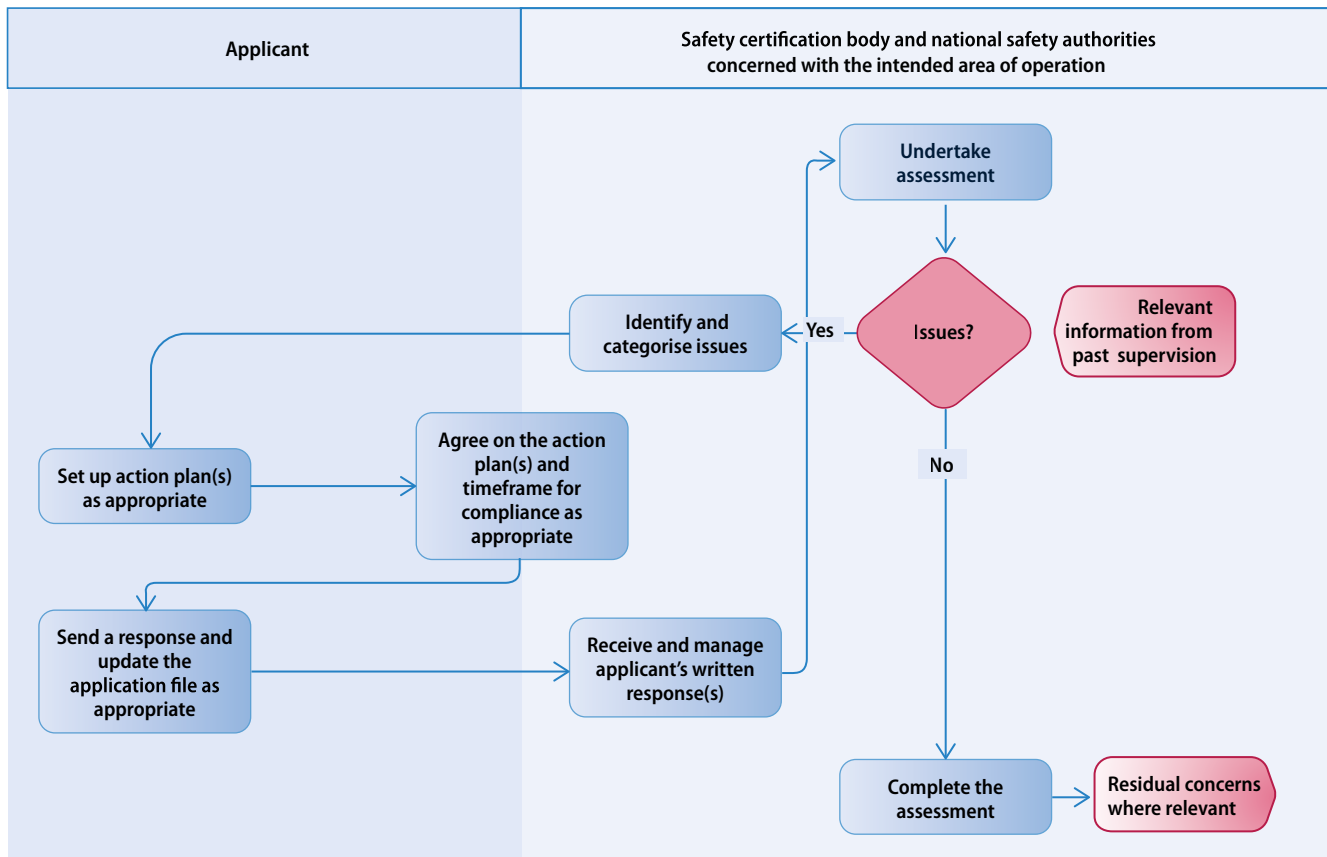
Before sending any request for further information that may affect the work of other authorities, the relevant authorities involved in the safety assessment should coordinate to discuss the draft issues logged in the issues log before submitting them to the applicant. Likewise, before rejecting the application or even taking the decision to proceed to the next stage, the authorities involved in the safety assessment should coordinate to discuss any pending issues relating to the initial screen stage and agree on the way forward. In any case, the decision over the completeness, relevance and consistency of the application is recorded by each authority involved in the safety assessment in their respective assessment reports. If no agreement can be reached between the different parties, the safety certification body takes a final decision on the completeness, relevance and consistency of the application. Each authority is however free to take its own decision and may request arbitration as appropriate.

The status of the initial screen stage is visible to all relevant parties, including the applicant, in the dashboard of the one-stop shop. The progress status of the stage, as reported individually by each authority is visible to all authorities in the dashboard, but not to the applicant. The summary of the initial screen and conclusions in relation to completeness of the file are recorded in the dedicated part of the assessment report by each of the authorities before starting the detailed assessment.

### 2.2.4. Detailed assessment

The detailed assessment starts after a positive decision on the completeness, relevance and consistency of the application. However, it does not prevent the authority involved in the safety assessment from undertaking the detailed assessment for its own part, even if other authorities involved have not yet completed the previous stage, provided that the coordination between authorities ascertains that the risk of rejecting the application is negligible.

Figure 4: The detailed assessment.



The detailed assessment covers the assessment of compliance with both the SMS requirements and the national rules.

The assessment of compliance with the SMS requirements falls within the competence of the safety certification body. The assessors may find useful guidance on how to perform this assessment in the *Agency guide on safety management system requirements*.

The assessment of compliance with the notified national rules falls within the competence of the national safety authority. For the intended area of operation, it includes checking the compliance with the requirements laid down in the notified national rules that relate to operational requirements not mandated in the applicable TSI OPE or in any other applicable European legislation. To help the applicant understand what is expected of it, the national

## 2. The safety assessment

safety authority is requested to publish and keep up to date an application guide, free of charge, describing and explaining the rules that are valid for the intended area of operation (including the scope of transposition of the safety directive) and the documents that the applicant has to submit.

As with the initial screen stage, any issues identified during the detailed assessment stage are managed through the issue log of the one-stop shop using the 4 issue types referred to in section 2.2.3. above. In general terms, any information relevant for the traceability of the decisions needs to be recorded and communicated to the applicant through the issue log.



Whenever the application is for a renewal or update of a single safety certificate, the conditions or restrictions of use of the previous certificate are to be considered during this stage of the assessment to verify whether they are still valid or if they should be lifted.

Similarly, this stage should be used to verify:

- ▶ possible issues deferred to supervision within the previous assessment, and
- ▶ the implementation of corresponding action plans by the applicant.

If there are outstanding issues raised from previous supervision, the authorities involved in the safety assessment should coordinate to decide whether they need to be recorded in the issue log.

Any differences of opinion among experts (including those experts belonging to the same authority) can also be recorded in the issue log.

When identifying a point of query (i.e. issues 'type 1') or a possible instance of non-compliance (i.e. issues 'type 3' and 'type 4'), the authorities involved in the safety assessment are encouraged to be as specific as possible, in order to assist the applicant in understanding the level of detail expected in the response without imposing particular actions to resolve it. Editorial or presentational concerns, or typographical errors, are not to be taken as evidence that the applicant has not demonstrated compliance unless they affect the clarity of the evidence provided by the applicant.

If all or parts of the application is deficient, the authorities involved in the safety assessment can request supplementary information from the applicant, using the issue log and specifying a timeframe for the expected response which is reasonable and proportionate to the difficulty of providing the information requested. In turn, the applicant provides the requested information through the issue log. If the applicant does not agree with the proposed timescale, it can still discuss it with the concerned authority, which in turn can decide to modify it using the issue log.

To be satisfactory, the applicant's written responses must be sufficient to allay the concerns expressed and to show that its proposed arrangements will meet the relevant requirements. It can submit new documents and/or rephrase parts of the originally submitted documents replacing what was unsatisfactory in the original application and including an explanation of how the revision deals with the identified deficiencies. The applicant may in addition supply relevant supporting information (e.g. SMS procedures). New and/or updated documents

are submitted through the issue log as attachments to respective issues. The applicant is responsible for identifying changes made to documents previously submitted (e.g. using track changes). This allows the assessors to check that the relevant parts of the documents have been modified accordingly and that other parts have not been changed.

Likewise, the applicant may propose measures to resolve issues and define timescales for their implementation. If the relevant authority does not agree with the proposed measures and/or timescales, it is invited to contact the applicant promptly to resolve the issue and record the decision in the issue log.

Where a response is largely satisfactory, but there is a residual concern, the authorities involved in the safety assessment should decide, each for its own part, to raise this residual concern with the applicant or agree to defer complete resolution to supervision after the issuing of the single safety certificate. Whichever route is taken, the authorities involved in the assessment should record, each for its own part, the decision with reasons in their respective assessment report. Thus the assessment report reflects the results of the assessment, including any differences of opinion amongst the assessors, residual concerns for consideration in later supervision and the opinion over whether to issue the single safety certificate.

If there are significant matters to be raised, an authority or several authorities in coordination with each other can request to meet the applicant to resolve outstanding matters and avoid multiple exchanges of correspondence. To that end, they confirm any pre-arranged date for this with the applicant or, otherwise arrange a date. In either case, confirmation has to be sent and an acknowledgement requested. This confirmation is sent with details of the matters of concern.

When such a meeting is deemed necessary, the objectives are set as follows:

- ▶ Ensure that the applicant has understood clearly the identified areas of non-compliance;
- ▶ Discuss what is required to remedy them;
- ▶ Agree the nature of the further information and any supporting evidence to be provided (action plan).

The authorities may also decide to undertake audits, inspections or visits (see also section 2.6) in order to collect additional evidence that cannot be retrieved from the documentary review of the application file and to get assurance that areas of concern not previously addressed by previous supervision as applicable have been adequately addressed by the applicant. For example, the authorities may decide to audit an applicant when there are doubts about how accurately the SMS reflect the company's operations, i.e. that the company does what is said in the SMS. In such a case an on-site audit, by interviewing staff, may help to collect evidence relevant to the safety certification body's knowledge about the submitted SMS. However, the main purpose of those audits, inspections, or visits should be to collect evidence to close out issues recorded within the assessment process.

Where the Agency acts as safety certification body, before a decision is taken about issuing of the single safety certificate, the authorities involved in the assessment should coordinate to discuss the content of their respective assessment reports. This should also include agreement

## 2. The safety assessment

on any restrictions and/or conditions of use as well as residual concerns to be deferred for later supervision, and set out which national safety authority will follow up the related actions. Following this coordination, the Agency should produce a final assessment report and identify the agreed restrictions and conditions of use to be included in the single safety certificate. Any diverging opinions between assessors will need to be managed by the project manager and they can be recorded in the assessment report if they remain unresolved.

Coordination between the relevant authorities involved in the safety assessment is also necessary if the identified non-compliances cannot be resolved, either because the applicant is unable to resolve the matter to the satisfaction of the authority or a timescale cannot be agreed. If the safety certification body confirms this conclusion, the application may be rejected.

The different authorities can still modify their respective assessment reports until the decision about issuing the single safety certificate is taken by the safety certification body and notified to the applicant.

### 2.2.5. Decision-making and closing of the assessment

The safety certification body prepares its decision in the one-stop shop, which is composed of a cover letter, the assessment report and the single safety certificate where applicable. When doing so, it checks that the documents are consistent with each other and with the application (unless it has been proposed to set restrictions and conditions of use) the information provided in the application form is reused in the single safety certificate.

The safety certification body is invited to review this information and update it with the outcome of the assessment with specific attention to changes in the area of operation and restrictions and/or conditions of use identified during the assessment.



Instructions on how the safety certification body should review and, when necessary, update the fields of the one-stop shop to produce a single safety certificate are provided in [Annex 5](#).



The date of receipt of the decision should correspond in the one-stop shop to the date of notification of the decision to the applicant. The deadline for requesting a review will be monitored against that date. Following the notification, the electronic version of the single safety certificate is automatically transferred by the one-stop shop into the ERADIS database. No specific action is required from the safety certification body.

When a paper version of the single safety certificate with handwritten signature and an official stamp of an organisation is required, the safety certification body can print it from the single safety certificate archived in the one-stop shop. This specific need is without prejudice to the above-mentioned date of the decision.

The authorities involved in the safety assessment should coordinate to identify lessons learned for use by future assessments and to improve their respective internal procedures. This can include results from internal/external audits and information on issues and risks as well as techniques that worked well that can be applied to future assessments and possibly shared with (or even learned from) other bodies for continual improvement.

Where the Agency acts as safety certification body, a national safety authority involved in the safety assessment can request a translation of the single safety certificate and the reasons for the decision. Whenever such translation is necessary, the national safety authority should submit its request at the decision-making stage at the latest. The Agency will translate documents at its own expenses and archive them in the one-stop shop.

When a paper version of the single safety certificate with handwritten signature and an official stamp of an organisation is required, the scanned copy of the single safety certificate is also archived in the one-stop shop.

### **2.3. Timeframe for the safety assessment**

Although not prescribed in law, where the Agency acts as safety certification body, the following intermediate milestones are proposed:

- ▶ Each authority assigns the competent resource no later than 1 week following the receipt of the application for a single safety certificate;
- ▶ Relevant information that has been collected in respect of the applicant's safety performance from past supervision activities is provided by the national safety authorities to the Agency at the latest when taking its decision regarding the completeness of the application.
- ▶ Each authority involved in the safety assessment concludes its own part of the detailed assessment no later than 5 working days before the agreed timeframe for taking the decision regarding the issuing of the single safety certificate, in order to give the Agency sufficient time to compile the different results and outcomes of the assessment.

### **2.4. Communication arrangements**

The safety certification body should manage the coordination of the different authorities throughout the safety assessment process. When meetings (face to face or tele/video conferences) or other coordination activities have to be organised, records are made by the safety certification body, with copies sent to all participants, and uploaded to the one-stop shop.

Coordination between parties involved in the safety assessment process is normally done in a mutually agreed language. This also includes the exchange of views between the Agency and national safety authorities with regard to the results and outcome of assessment as well as any other communication.

Upon request of the national safety authority (or authorities) for the area of operation, the Agency acting as safety certification body can translate its decision and the reasons for it in the language of the national safety authority (or authorities). The translation request is managed outside the safety assessment process, without any cost for the applicant.

### 2.5. Quality assurance

The safety certification body is responsible for ensuring that:

- ▶ The different stages of the process have been correctly applied;
- ▶ There is sufficient evidence to show that all relevant aspects of the application have been assessed;
- ▶ The applicant has responded to all matters of non-compliance (i.e. 'type 3' and 'type 4' issues) and any other requests for further information have been received from the applicant;
- ▶ Type 3 and type 4 issues were all resolved or, where not resolved, the reasons for this were clearly documented;
- ▶ Residual concern for supervision are assigned to and agreed with the competent national safety authority;
- ▶ The decisions made are documented, fair and consistent;
- ▶ The opinion over the issue of the single safety certificate, given in the assessment report, reflect the assessment as a whole.

If the conclusion is that the process has been properly followed it will be sufficient to confirm that the above steps have been followed, accompanied by any qualifying comments. If the conclusion is that it has not, then the reasons for reaching this conclusion should be stated clearly.

### 2.6. Audits, inspections or visits

**Where the Agency acts as a safety certification body**, the objectives and scope of audits, inspections or visits and the role assigned to each authority involved has to be coordinated in order to avoid duplication of effort and to reduce the possibility of requiring the applicant to accommodate multiple audits, inspections or visits. When the Agency conducts an audit, inspection or visit, the relevant national safety authority (or authorities) provides the necessary support and assistance to the Agency in order to meet any applicable safety rules in force on the site(s) of the applicant.

The authority undertaking an audit, inspection or visit is expected to have internal arrangements or procedures setting out the framework for delivering it. For that purpose, it may decide on a voluntary basis to apply the principles and requirements established by relevant standards such as ISO 19011 and ISO 17021 for the conduct of management system audits and ISO 17020 for the inspections.

Findings from audits, inspections or visits are evidence that may support the closing of issues recorded in the issue log. However, in some cases, they may cover issues (e.g. instances of non-compliance) not previously identified and in that case they are to be recorded in the issue log as new issues.

More detailed information regarding the audit and inspection techniques can be found in the *Agency guide on supervision*.

## 2.7. Interface between assessment and supervision

National safety authorities are invited to use the supervision summary form when discussing outstanding issues identified during previous supervision that are of relevance for the safety assessment.

In particular, when an application has been received for the renewal or update of the single safety certificate, the national safety authorities are requested to provide the safety certification body with the results of any follow-up in relation to residual concerns that have been deferred to supervision. This information allows the safety certification body to close out the residual concerns in the one-stop-shop.

More detailed information can be found in the *Agency guide on supervision*.

## 2.8. Training centre, entities in charge of maintenance and transport of dangerous goods

In accordance with Article 5 of Commission Decision 2011/765/EU and Article 13(2) of Directive (EU) 2016/798, the recognition of a training center which belongs to a railway undertaking can be stated on its single safety certificate in the case where the following preconditions are fulfilled:

- ▶ The railway undertaking is not the only training provider on the market;
- ▶ The railway undertaking provides training only to its own staff.

In such a case, it is recommended that the relevant national safety authority confirms the recognition of the railway undertaking's training centre in its assessment report and that the statement of recognition is displayed on the single safety certificate even if that national safety authority is not the safety certification body.

Railway undertakings acting as entities in charge of maintenance (ECMs) and maintaining vehicles exclusively for their own operations do not have an obligation to hold an 'ECM certificate' in accordance with Article 3(2)(b) of Commission Implementation Regulation (EU) 779/2019. However, their maintenance system must still comply with Annex II to this Regulation. Evidence of compliance with this Annex must be provided by these railway undertakings when applying for a single safety certificate.

Where the applicant has indicated dangerous goods as part of the scope of operations the SCB should be aware that it must consult with the competent authority for the carriage of dangerous goods by rail as to compliance with the relevant legislation. Where ERA is the SCB this consultation will be carried out via the relevant NSA(s) for the area of operation.



## 3. Arbitration and appeal

### 3.1.1. Arbitration

Where the Agency disagrees with a negative assessment carried out by one or more national safety authorities, it informs that authority or authorities in question, giving reasons for its disagreement. The Agency and the national safety authority or authorities cooperate with a view to agreeing on a mutually acceptable assessment. Where necessary, the Agency and the national safety authority or authorities may decide to involve the railway undertaking.

If no mutually acceptable assessment can be agreed on within 1 month after the Agency has informed the national safety authority or authorities of its disagreement, the national safety authority or authorities may refer the matter for arbitration to the Board of Appeal.

Requests for arbitration are addressed to the Board(s) of Appeal. The proceedings are registered by the Registrar of the Board(s) of Appeal in the one-stop shop.

The Board of Appeal dealing with the arbitration case has access to the complete application file available in the one-stop shop. The Board of Appeal decides whether to confirm the Agency's draft decision within 1 month of the request for arbitration of the national safety authority or authorities.

The decision of the Board of Appeal is notified to all parties involved in the safety assessment, including the applicant, through the one-stop shop.

The same arbitration procedure also applies in the event of a disagreement between the Agency and the national safety authority when the latter finds during its supervision that the holder of a single safety certificate issued by the Agency no longer satisfies the conditions for certification and asks the Agency, as safety certification body, to restrict or revoke the certificate.

Considering that the arbitration procedure would lead to an extension of the timeframe of the assessment, the Agency specifies the different milestones relating to the arbitration in the dashboard of the one-stop shop (see also section 2.3).

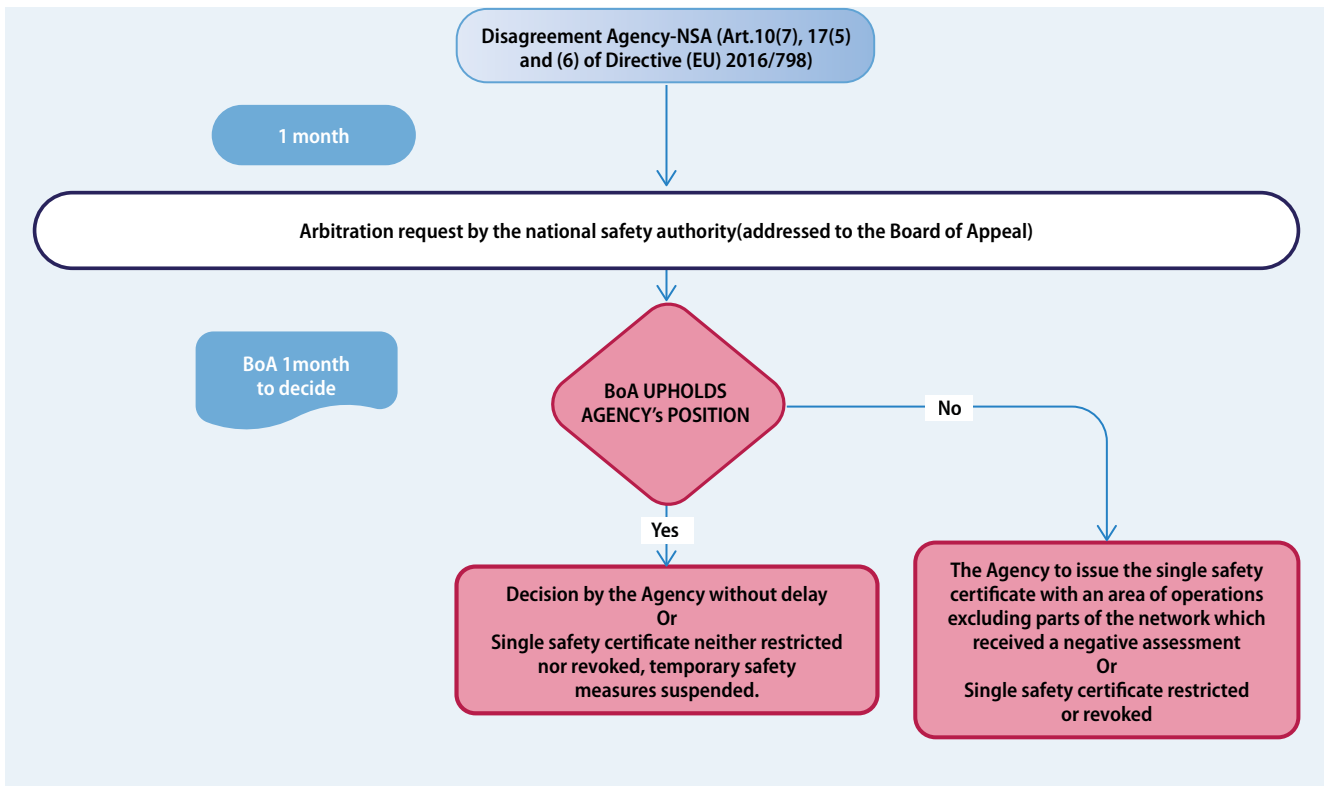
### 3.1.2. Appeal

In the case where the Agency is the safety certification body, after the submission of an appeal to the Board of Appeal, the Registrar of the Board of Appeal records the appeal request in the one-stop shop.

An appeal against a negative decision of the safety certification body can be brought either by an applicant or by any other interested party, including the national safety authority as appropriate. A negative decision includes the rejection of the application or the issue of the single safety certificate with restrictions and/or conditions of use other than those defined in the application.

The procedural rules applicable to the appeal are further detailed in Commission Implementing Regulation (EU) 2018/867 [*rules of procedure of the Board(s) of Appeal of the Agency*].

Figure 5: Flowchart of the arbitration procedure



## 4. Restricting or revoking a single safety certificate

A single safety certificate may be restricted or revoked by the safety certification body that has issued it.

Any national safety authority concerned with the area of operation can request the Agency acting as safety certification body to restrict or revoke a single safety certificate in accordance with Articles 17(5) and (6) of Directive (EU) 2016/798. The request to restrict a single safety certificate can be submitted by that national safety authority in the one-stop shop while the request to revoke a valid single safety certificate is to be submitted by e-mail to the Agency programme manager. The Agency may consider that the request to restrict or revoke the single safety certificate is not well founded or that the temporary safety measures applied by the national safety authority are disproportionate. In any cases, the Agency notifies the national safety authority of its decision. Any revocation request must be submitted through ERADIS by the safety certification body in accordance with existing procedures.

## 5. Reviewing a decision

The applicant may decide to request a review of a negative decision issued by the safety certification body, which includes the refusal of the single safety certificate, the exclusion of part of the network in accordance with a negative assessment as referred to in Article 10(7) of Directive (EU) 2016/798 and the identification of restrictions or conditions of use other than those requested in the application.

The review request is a step prior to the appeal before the appeal body.

The safety certification body has two months from the date of receipt of the request for review in which to confirm or reverse its decision. In any cases, the safety certification body is invited to coordinate with the national safety authority (or authorities) concerned with the area of operation before taking its decision. Following the outcome of that coordination, the safety certification body and the national safety authority (or authorities) concerned with the area of operation may amend their respective assessment report or append to their report a justification for confirming or reversing their first decision.

The safety certification body notifies the applicant of its decision using the one-stop shop.

## ANNEX 1

# List of issues to be covered in the national safety authority application guide

The national safety authorities are invited to cover the following issues in their application guides in respect of their national requirements, in accordance with Article 10(3)(b) of Directive (EU) 2016/798:

1. The scope of the national measures implementing Directive (EU) 2016/798 – The national safety authority identifies any possible exclusions applicable in their Member State, according to Article 2.3 of the Directive. It clarifies specific national requirements in relation to the type(s) of operation that require(s) holding a single safety certificate;
2. Language policy – Describe the applicable language for the application file where the national safety authority is selected as safety certification body and for the national part of the application file where the Agency is selected as safety certification body;
3. Communication arrangements – Describe what and how the national safety authority intends to communicate with the applicant in the case where the national safety authority is selected as safety certification body;
4. Fees and Charges – Describe the model for fees and charges in the case where the national safety authority is selected as safety certification body and the hourly rate applied by the national safety authority for the assessment of the national part in the cases where the Agency is selected as safety certification body;
5. Description of cross-border agreements and identification of border stations covered by these agreements;
6. Description and explanation of requirements laid down in the notified national rules, using the model template provided for in the [Appendix](#), and applicable national administrative procedures– The national safety authority describes and explains the requirements of the notified national rules by recording them in the template provided in the [Appendix](#). Any applicable national procedural rules should also be clarified, as this may, for example, relate to specific arrangements or may explain how national certification schemes could serve as proof of the ability of the applicant to meet requirements of the notified national rules. Additionally, the national safety authority will instruct the applicant on how to map its evidence with the national requirements. This mapping can be done through:
  - ▶ a web-form having the requirements pre-registered by the NSA in the one-stop shop. This is the preferred option,
  - ▶ an available web-form in the one-stop-shop, where the applicant registers by himself the relevant national requirements, as described by the NSA in its national application guide, or
  - ▶ a template provided by the NSA in its national application guide. The applicant in this case uploads this document to the one-stop shop;

- 7.** Minimum insurance requirements (where applicable) such as the need to send evidence of insurance or financial cover for liability;
- 8.** National appeal procedure for the cases where the national safety authority is selected as safety certification body;
- 9.** National provisions regarding judicial review for the cases where the national safety authority is selected as safety certification body.

Appendix  
**Model template of mapping table against the requirements laid down in the national rules**

<b>To be completed by the national safety authority</b>		<b>To be completed by the applicant for the single safety certificate</b>	
<b>Reference</b> (Reference to the applicable notified national safety rule)	<b>Requirements</b> (Headline of the requirement laid down in the applicable notified national safety rule)	<b>Documentary evidence</b> (Document reference / version / date / chapter / section etc.)	<b>Description</b> (Brief description of the document)

## ANNEX 2

# Instructions on how the safety certification body fills in the fields of the one-stop shop to produce a single safety certificate

When a single safety certificate is to be issued, the safety certification body has to fill in the relevant fields of the one-stop shop (OSS). The following table provides instructions on how to do this, using the same numbering as the one-stop shop.

**Table 3:** Instructions on how the safety certification body reviews and when necessary, updates the fields of the one-stop shop to produce a single safety certificate

<i>Field name</i>	<i>Commentary</i>
<b>1. Certificate information:</b>	
1.1 European Identification Number	The EIN is automatically generated.
1.2 Type of certificate	New, renewal or update: it is automatically filled in by the OSS, based on the information available in the relevant application form, and may be edited by the safety certification body.
1.3 Previous certificate	This is automatically filled in by the OSS based on the information available in the relevant application form, and may be edited by the safety certification body. The safety certification body is invited to check that this information is accurate.
1.4 Validity period:	The safety certification body specifies the validity period. The start validity date does not necessarily correspond with the date of the decision about issuing the SSC, but aligned with the start of operation, as requested by the applicant or the expiry dates of the previous certificate. The OSS automatically calculates 5 years using the start validity date that has been entered. The safety certification body may update it.
<b>2. Railway undertaking:</b>	
2.1 Legal denomination	The railway undertaking will be identified by its legal denomination. This field is automatically filled in by the OSS based on the information available in the relevant application form and may be edited by the safety certification body.
2.2 National registration number	This is automatically filled in by the OSS based on the information available in the relevant application form and may be edited by the safety certification body.
2.3 VAT number	This is automatically filled in by the OSS based on the information available in the relevant application form and may be edited by the safety certification body.
<b>3. Safety certification body:</b>	
3.1 Organisation	This is automatically filled in by the OSS and may be edited by the safety certification body.



<i>Field name</i>	<i>Commentary</i>
3.2 Member State	This is automatically filled in by the OSS and may be edited by the safety certification body.
<b>4. Content of the certificate:</b>	
4.1 Type of operation	This is automatically filled in by the OSS and may be edited by the safety certification body.
4.2 Area of operation	This is automatically filled in by the OSS and may be edited by the safety certification body.
4.3 Operations to border stations	This is automatically filled in by the OSS, based on the application form submitted by the applicant and may be edited by the safety certification body. The safety certification body checks that the list of border stations is compatible with the outcomes of the assessment.
4.4 Restrictions and conditions of use	Here the one-stop shop allows the safety certification body to identify possible restrictions or conditions of use that have been agreed during the assessment.
4.5 Applicable national legislation	When specifying the applicable national legislation the authorities involved in the safety assessment are encouraged to identify specific exclusions from Directive (EU) 2016/798 applicable to their respective Member States which are relevant for the type and extent of operations. If more details are needed, they may still be provided in the field 4.6 "Additional information" of the single safety certificate.
4.6 Additional information	The authorities may use this field to add other information relevant to the authorities, such as additional types of operation as required by the national legislation (see point 4.5), the entity in charge of maintenance role, or the role of an accredited or recognised training center undertaken by the railway undertaking.
<b>5. Issuing date and signature:</b>	The date is automatically generated by the OSS when the document is signed.



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### Guidance for Safety certification:

- ▶ Application guide for the granting of single safety certificates — A guide for the applicants
- ▶ **Application guide for the granting of single safety certificates — A guide for the authorities**
- ▶ Safety management system requirements for safety certification or safety authorisation
- ▶ Supervision guide
- ▶ Management maturity model
- ▶ Enforcement management model
- ▶ Coordination between national safety authorities – A common approach to supervision
- ▶ Competence management framework for authorities