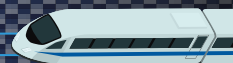


**Guidance for safety
certification and
supervision**



Application guide for the granting of single safety certificates

A guide for the applicants

The present document is a non-legally binding guidance of the European Railway Agency. It is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

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Guidance for safety certification and supervision

Application guide for the granting of single safety certificates

A guide for the applicants

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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 that has been developed in collaboration with national safety authorities and sector representatives. It 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.

1.1. Purpose of the guide

This guidance document is aimed at assisting the railway undertakings applying for a single safety certificate to understand the process.

It describes in particular:

- ▶ The conditions of application for a single safety certificate;
- ▶ The process for the application for a single safety certificate;
- ▶ The structure and content of the application file to be submitted by the railway undertaking;
- ▶ The details of the safety assessment;
- ▶ The conditions for updating or renewing a single safety certificate; and
- ▶ The conditions for restricting or revoking a single safety certificate.

1.2. Who is this guide for?

This document is addressed to the railway undertakings (also named hereinafter the ‘applicant’) who want to submit an application for a single safety certificate.

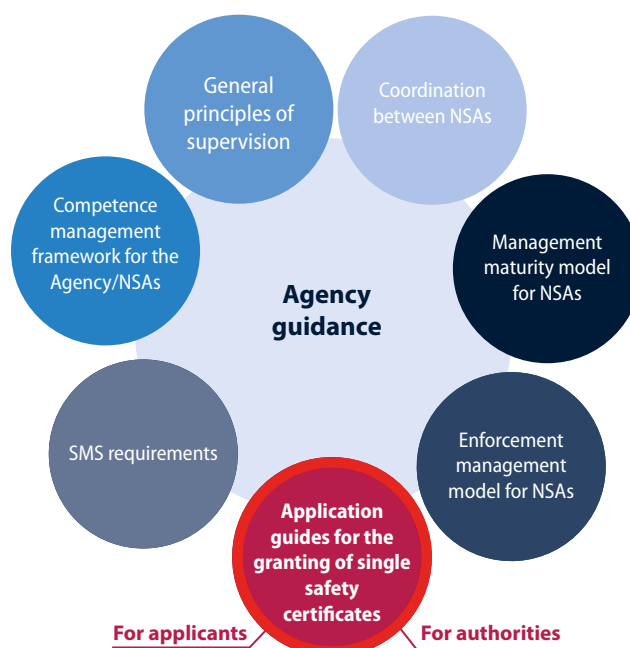
1.3. Scope

This document provides detailed practical information that is primarily intended to support applicants in understanding the requirements regarding single safety certificates, as stipulated in the European legal framework. This guide is supplemented by the application guide of the national safety authority. The national safety authority guide should describe and explain 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 national safety authority decisions.

1.4. Guidance structure

This document is one of the two guides that the Agency has published covering the granting of single safety certificates, the other being *the application guide for the authorities*. 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

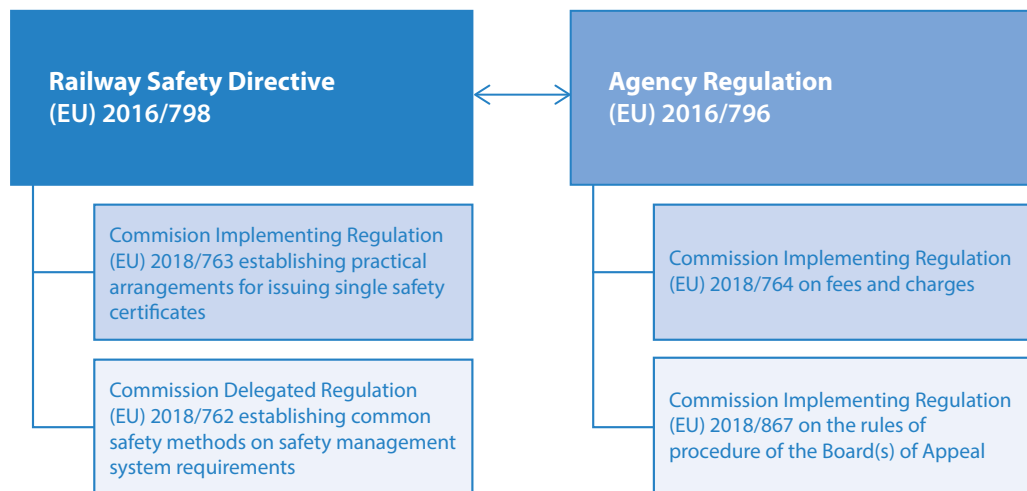
Directive (EU) 2016/798 on railway safety is one of the three legislative acts that form the technical pillar of the 4th Railway Package. It aims at the simplification and harmonisation of the safety assessment process to benefit the applicants who apply for a single safety certificate by reducing the burden and costs being borne by them, 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



The **Agency Regulation (EU) 2016/796**, 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.

1. Introduction

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. Conditions of application for a single safety certificate

Directive (EU) 2016/798 applies to the rail system in the Member States and requires a railway undertaking to hold a single safety certificate in order to obtain access to the railway infrastructure of one or more Member States, according to its declared area of operation.

The railway undertakings whose principal business is to transport goods and/or passengers, whether or not their activities are limited to providing traction only, shall have a licence according to Directive 2012/34/EU. For these railway undertakings, possession of a valid licence and a single safety certificate are the conditions to be met before being granted access to the railway infrastructure.

The provisions of Directive (EU) 2016/798 are valid only for those railway companies that fall within its scope, which depends on how this Directive has been transposed in the Member States. Member States may identify exclusions from the scope of Directive (EU) 2016/798 and therefore a single safety certificate may not be needed in the following cases:

- (a) *privately owned railway infrastructure, including sidings, used by the owner or by an operator for the purpose of their respective freight activities or for the transport of persons for non-commercial purposes, and vehicles used exclusively on such infrastructure;*
- (b) *infrastructure and vehicles reserved for strictly local, historical or tourist use;*
- (c) *light rail infrastructure occasionally used by heavy rail vehicles under the operational conditions of the light rail system, where it is necessary for the purposes of connectivity of those vehicles only; and*
- (d) *vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit to be effected on a confined and limited section of heavy rail infrastructure for connectivity purposes only.*

National safety authorities are asked to state and explain in their respective application guides whether one or more of the above exclusions are applicable in their Member States.

It may happen that, for the intended area of operation, the exclusions established by the relevant Member State(s) are not the same. For example, operations in sidings on privately owned railway infrastructure may be excluded from the scope of Directive (EU) 2016/798 in one Member State but not in another Member State. In such cases it is important that the railway undertaking describes and explains in its application file the type(s) of operation in each Member State where it intends to operate, detailing also any specific national requirements related to the type(s) of operation where relevant (see also point 2.6 in the Annex).

2. Conditions of application for a single safety certificate

In any case, the application for a single safety certificate must always cover the type(s) of operation for the relevant area of operation. For example, a railway undertaking that provides only traction for the haulage of freight wagons must hold a single safety certificate for freight services (including or excluding the transport of dangerous goods). If the same undertaking wants to provide traction for the haulage of passenger coaches as well then it must hold a single safety certificate for freight and passenger transport (including or excluding the transport of dangerous goods and including or excluding high-speed services). Companies operating track maintenance vehicles on the railway network that falls in the scope of the Directive (EU) 2016/798 must be covered by a safety management system. This can be done either by operating under their own single safety certificate or by providing their services as subcontractors to the infrastructure manager and by operating through its safety management system. In this second case, the infrastructure manager is fully responsible for the products delivered or the services supplied and its subcontractor is not required to have a single safety certificate.

Similar cases where the same company is not treated with the same approach to safety certification across Member States (i.e. a single safety certificate can be required in one Member State for a specific type of operation while in other Member States a certificate is not required for the same type of operation) may occur although a harmonised and consistent approach is to be sought at Union level.

Infrastructure managers may need to use - within the limit of their activities - trains, infrastructure inspection vehicles, on-track machines or other special vehicles for different purposes, such as the transport of materials and/or staff for construction or infrastructure maintenance, the maintenance of its infrastructure assets or the management of emergency situations. In such cases, the infrastructure manager is deemed to operate in the capacity of a railway undertaking under its safety management system and safety authorisation without the need to apply for a separate single safety certificate, irrespective of whether it owns the vehicles or not.



Activities performed in sidings, such as the loading of wagons, are industrial activities that interface with specific railway activities such as the composition, preparation and movement of rakes of vehicles that can be trains or will be used in trains. This includes the coupling of different vehicles to form rakes of vehicles or trains and moving them. No movement of trains or rakes of vehicles can be made on the rail network under the responsibility of an infrastructure manager if they are not covered by a single safety certificate (or a safety authorisation). It means that such movements can only be carried out by railway undertakings (or infrastructure managers) having valid safety certificates (or safety authorisations) or by any other organisation acting as subcontractor for those railway undertakings (or infrastructure managers) and operating under their SMS.



3. How to apply for a single safety certificate?

3.1. Submission of the application (1)

The railway undertaking is requested to submit any application for a single safety certificate through the single entry point of the one-stop shop, available from the [Agency website](#).



It is recommended that an application for a single safety certificate is submitted **at least 6 months** before:

- (a) *the planned start date of any new rail transport operation which requires a **new** single safety certificate;*
- (b) *the planned start date of a rail transport operation following one or more substantial changes made to the type, extent or area of operation which requires an **update** of the single safety certificate; or*
- (c) *the end of the period of validity of the current single safety certificate which requires a **renewal** of the single safety certificate for the continuity of the rail operations.*

This timeframe aims at mitigating potential risks associated with prolonging the time taken for the assessment, for example if the application file is not satisfactory and additional time is needed by the applicant to provide supplementary information. This could prevent the operation starting on a planned date or could impair the business continuity of an already-certified railway undertaking (see also section 6.3).

An application for a single safety certificate may be rejected in the following situations:

- (a) *If the applicant submits an application (new, update or renewal) while another application is already ongoing, irrespective of the type, extent and area of operation;*
- (b) *If the applicant already holds a valid single safety certificate issued by a safety certification body and wishes to extend its area of operation in other Member State(s) by applying for a new single safety certificate in the Member State(s) affected by the extended area of operation;*
- (c) *If the applicant already holds a valid single safety certificate and submits an application for a “new” certificate irrespective of the type, extent and area of operation;*
- (d) *If a valid single safety certificate does not already exist for an applicant who is submitting a renewal or update application.*

If any of the above situations occurs the one-stop shop provides an early warning to the applicant before the submission of its application, requesting appropriate changes.

If, despite the early warning, the application is submitted to the one-stop shop, the safety certification body is invited to contact the applicant and seek more information. Depending on the explanations provided by the applicant, the safety certification body may reject the application or terminate the application upon request of the applicant.

(1) Before the submission of the application it is recommended for the applicant to request a pre-engagement from the safety certification body.

3. How to apply for a single safety certificate?

During the transition from the regulatory regime under Railway Safety Directive 2004/49/EC to the regulatory regime under Railway Safety Directive (EU) 2016/798, a warning is also issued when an applicant holding more than one Part A safety certificate applies for an update or renewal for only one. This warning is to inform the applicant that the new single safety certificate will replace all valid certificates. It should be noted that all first applications for a single safety certificate whether the applicant has held a previous 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.

In general, once an application is submitted in the one-stop shop it cannot be amended unless the applicant requests it. In the course of the assessment the applicant may also request termination of its application, e.g. to reduce the cost if it concludes that the application is not sufficient to get a positive assessment. These requests have to be formally addressed to the safety certification body and submitted through the issue log of the one-stop shop (see section 3.2).

The applicant can start a new application from a previous pre-engagement request (see section 6.1.1) or application. This may be particularly useful to avoid inconsistencies between different applications and to speed up the submission process.

3.2. The one-stop shop

The one-stop shop is an IT platform managed by the Agency, available in all the official languages of the Union, through which all applications for a single safety certificate are to be submitted.

In order to submit an application for a single safety certificate, the applicant needs to have a registered user of the one-stop shop. By definition, a user is a natural person appointed by the applicant to manage the application process in the one-stop shop. It is highly recommended that this registered user is someone from within the applicant's organisation, and the organisation puts in place measures to make sure that there is always a registered user. At the same time, the user submitting an application in the one-stop shop becomes the contact person to whom all the communication relevant for the application is addressed. The applicant's contact person may however give rights to other persons within (or external to) its organisation to access the application. The management of users within the applicant's organisation and related access rights to applications is the sole responsibility of the applicant.

The issue log is a feature of the one-stop shop that serves as a means of communication between the authorities and the applicant during the course of the safety assessment process. Once an application is submitted the authorities will use the issue log to register all issues identified and the applicant will be requested to address them by providing its response directly in the issue log. An applicant may also create issues in the issue log, especially when it wants to request the termination or limitation of scope of its application.

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. When several authorities are involved in the safety assessment the conclusions of the different authorities are compiled by the Agency, and the final outcome is communicated to the applicant through the one-stop shop.

The one-stop shop also ensures the configuration management of all uploaded documents. An applicant has read-only access to its application file and the results and outcome of the assessment, including the single safety certificate as appropriate. However, an applicant can also submit new or revised documents at the request of the authorities during the course of the assessment.

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.

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.

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

3.3. Selection of the safety certification body

Where its area of operation is limited to one Member State, the applicant can choose in the one-stop shop which authority, either the Agency or the national safety authority of the Member State concerned, will be responsible for issuing the single safety certificate.

3. How to apply for a single safety certificate?

Railway undertakings may operate services as far as border stations in neighbouring Member States. Such cases do not require an extension of the area of operation when the network characteristics and the operating rules are similar and therefore, following consultation and agreement with the relevant national safety authorities, can be assimilated into an operation otherwise limited to one Member State. The applicant is requested to identify in its application such border stations, where relevant (see also section 5).

Where the area of operation is not limited to one Member State the Agency is the safety certification body by default, and therefore in this case the applicant is not able to change the certification body identified in the one-stop shop.

The choice of the safety certification body is binding until the safety assessment process is completed or terminated, which means that the applicant is not able to change it once its application for a single safety certificate is submitted in the one-stop shop.

During the pre-engagement (see section 6.1.1), in the case where the area of operation is limited to one Member State, the applicant may decide to address its request to another authority. In such a case, a new request for pre-engagement must be submitted in the one-stop shop after the first request is terminated.

3.4. Language policy

Where a national safety authority acts as safety certification body, the language to be used for the application file must be an official language of the Member State for the intended area of operation, as indicated in the application guide of the competent national safety authority.

Where the Agency acts as safety certification body, the language to be used for the application is as follows:

- ▶ For the part of the application file relating to the establishment of the safety management system: one of the official languages of the Union;
- ▶ For the part of the application file relating to the demonstration of compliance with the notified national rules: the language determined by the Member State for the intended area of operation and indicated in the application guide of the competent national safety authority.

Any national safety authority for the intended area of operation may require the applicant to provide translation of the parts of documents relevant for checking the compliance with applicable national rules into a language accepted by the national safety authority. This requirement is, however, limited to a description or any other demonstration of how the safety management arrangements address the requirements of the notified national rules and does not allow the national safety authority to request a translation of the whole safety management system.

The applicant is advised to anticipate the needs for translation while planning its application for a single safety certificate.

3.5. Fees and charges

In the case where the national safety authority acts as safety certification body, the fees and charges are levied by the national safety authority in accordance with its national legislation. Further information can be found in the application guide of the competent national safety authority.

In the case where the Agency acts as safety certification body, the fees and charges levied by the Agency for the purposes of issuing new, updated or renewed single safety certificates are in accordance with Commission Implementing Regulation (EU) 2018/764 *on the fees and charges payable to the European Union Agency for railways and their conditions of payment*.



Fees and charges are defined as follows:

- ▶ **Fees:** Amounts levied to obtain, maintain, update or revoke single safety certificates;
- ▶ **Charges:** Amounts levied for other services such as pre-engagement, audits, inspections or visits.

The calculation of fees and charges is the total of:

- ▶ the number of hours spent by the Agency on the processing of the application multiplied by the hourly rate of the Agency; and ,
- ▶ the relevant costs of the NSAs resulting from the processing of the national part of the application.

The Agency's hourly rate is set to balance both its direct costs (e.g. staff salary, travel expenses) and indirect costs (e.g. management/support services such as secretariat, finance and overhead costs). The costs for audits are not included in the formula and are charged separately.

Any pre-engagement activities (see section 6.1.1) are charged in accordance with the above formula.

In the case of rejection or termination of the application upon request of the applicant, the fees and charges incurred for the services already delivered are to be borne by the applicant.

Where the Agency is the safety certification body, the notification of invoicing is managed through the the one-stop shop. The invoice is uploaded to the file and the notification, together with information on the deadline for the payment is sent to the registered user as appointed by the applicant to manage the application file. The notification process follows the same principles as notification of issues. The deadline for the payment is set, in accordance with the IA on fees and charges, to 60 calendar days from the date on which the invoice is notified to the applicant.

Please note that an applicant applying to the Agency, has to include in its application, unless already included in a previous application and is still valid, a signed Legal Entity Form (LEF) with its supporting evidence in order to prove their legal capacity and their status.

4. Training centres, entities in charge of maintenance, and 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. If the applicant fulfils the conditions above it must indicate in its application using the other information field in the application form if it wants to be recognized as a training centre as part of the application for a single safety certificate.

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 Regulation (EU) 779/2019. Appropriate evidence of compliance with the Annex must be provided by the railway undertaking when applying for a single safety certificate in support of such an application.

Where the applicant has indicated dangerous goods as part of the scope of operations the applicant should be aware that the safety certification body will consult with the competent authority for the carriage of dangerous goods by rail. Where the Agency is the safety certification body this consultation will be carried out via the relevant NSA(s) for the area of operation. The applicant will be expected to identify the competent authority for transport of dangerous goods and to provide in the one-stop shop the necessary evidence of compliance with the transport of dangerous goods by rail regulations as part of its safety management system.

5. Structure and content of the application file

The application file consists of:

- ▶ the application form;
- ▶ a signed Legal Entity Form (LEF) with its supporting evidence in order to prove legal capacity and status². When the applicant has a dedicated address for invoicing, it is advised to include this information in a separate file and upload it in the one-stop shop;
- ▶ documentary evidence that the applicant has established its safety management system in accordance with Article 10(3)(a) of Directive (EU) 2016/798;
- ▶ documentary evidence that the applicant meets the requirements laid down in the relevant national rules notified in accordance with Article 8 of Directive (EU) 2016/798;
- ▶ cross referencing within the safety management system documentation to identify the location of the evidence that the relevant requirements of the CSMS on SMS, the applicable Technical Specification for Interoperability relating to the operation and traffic management subsystem, and the applicable national rules are met; and
- ▶ the current status of the corrective action plan (or plans) to resolve any major non-compliances or other areas of concern identified during supervision activities that have taken place since the previous assessment. In the case of an application for the renewal or update of an existing single safety certificate this should include residual concerns from previous assessments, where relevant.

The application file must be submitted electronically through the one-stop shop, using the web forms provided by the system. Instructions for use with regard to the content of the application for a single safety certificate are provided in the Annex to this guide.

The application must be concise and self-contained with all relevant information provided within it.

Using the electronic checklists or templates available in the one-stop shop, the applicant is requested to map separately its documentary evidence against:

- ▶ the requirements set out in Annex I of the CSMS on SMS (more information on these requirements may be found in the Agency's guide on SMS requirement) ;
- ▶ the requirements of the applicable Technical Specification for Interoperability relating to the operation and traffic management subsystem (TSI OPE); and
- ▶ the requirements laid down in the applicable national rules for each Member State affected by the area of operation.

⁽²⁾ Legal Entity Form to be submitted only for a first application and when the Agency is safety certification body.

5. Structure and content of the application file

The above checklists (or correlation tables) allow for the indexing of information so that the assessor can easily find it, including links to supporting documents. Other documents can be referenced so that:

- ▶ the assessor can have confidence that they exist and can check them if necessary; and
- ▶ they can be requested for examination after the issue of the single safety certificate during subsequent supervision.

An application may reproduce extracts from the relevant documents within the body of its text, but in general, the assessor does not need to refer to other documents to obtain the required evidence.

Each national safety authority is requested to describe and explain in its application guide the requirements laid down in the national rules notified by its Member State.

As a general rule, an application for a renewal or an update of the single safety certificate still includes all the constituent elements of an application file. However, the applicant is asked to identify and describe the changes to the documentary evidence sent since the previous application (for which a single safety certificate was granted). To help identify the changes made to the documentary evidence, the applicant is advised to both mark the changes in the updated documents and provide explanation of those changes. A simplified process is envisaged for specific changes of an administrative nature.



6. The safety assessment

6.1. Safety assessment process

The safety assessment process contains the following stages:



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

The safety assessment process is iterative, as shown in Figure 3. This means that the authorities for the intended area of operation are entitled to make reasonable requests for further information or re-submission of elements of the application during the course of the assessment.

More detailed information on the safety assessment process can be found in the *Agency application guide for the granting of single safety certificates – A guide for the authorities*.

6.1.1. Pre-engagement

It is highly recommended that the applicant requests pre-engagement through the one-stop shop before submitting its application for a single safety certificate (new, update and renewal) in order to help understand what is expected and to mitigate at the earliest possible stage the risks of delays in issuing the single safety certificate which could impair business continuity.

The pre-engagement is aimed at:

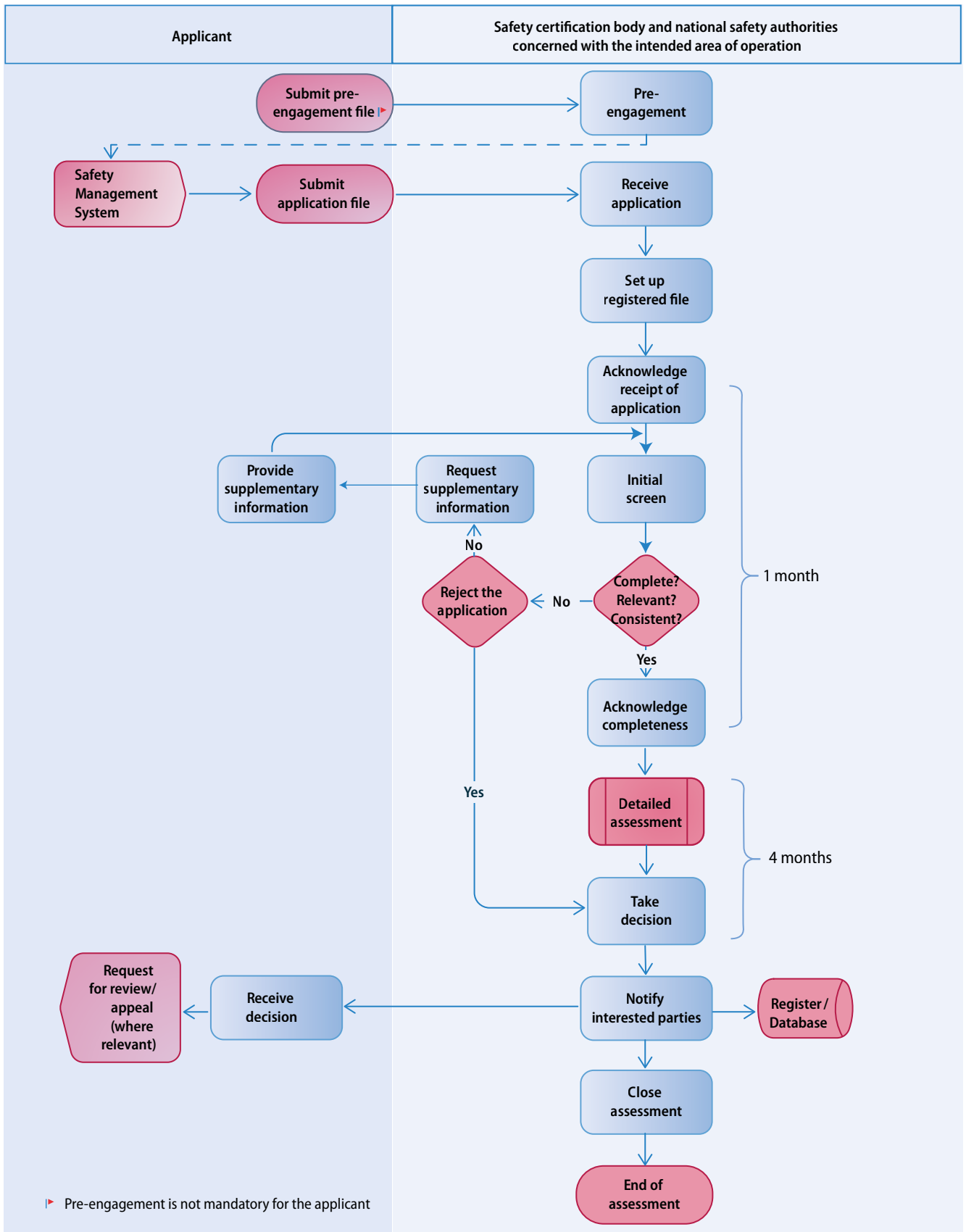
- ▶ Facilitating early contact;
- ▶ Developing the relationship between assessor(s) and applicant;
- ▶ Gaining familiarity with applicant's safety management system; and
- ▶ Verifying that the applicant has been provided with sufficient information to know what is expected, the way the assessment process will be conducted and how decisions will be made.



The pre-engagement stage is not mandatory for the applicant but is recommended as it mitigates potential risks at the assessment stage and facilitates the assessment process itself. If it wishes, the applicant can still submit its application for a single safety certificate without pre-engagement. However, if the applicant requests a pre-engagement, the different authorities for the area of operation are required to participate.

6. The safety assessment

Figure 3: The safety assessment process



It is recommended that pre-engagement starts well before the planned date of submission of the application for a single safety certificate. For complex projects this might be **a year or more** before the submission of the application in order to ensure an effective exchange of information between the different parties and to allow sufficient time for the applicant to implement any necessary changes to the application. The pre-engagement duration is expected to be proportionate to the size and complexity of the intended application.

To make pre-engagement effective in achieving its full benefits, the applicant is required to submit a file to the safety certification body that includes an overview of its SMS at the same time as it requests pre-engagement. The file must include the information listed in items 1 -6 of Annex 1 of Commission Implementing Regulation (EU) 2018/763 but the amount of information provided is not limited to this list. In addition the applicant is requested to set the agenda(s) and to keep records of the pre-engagement meeting (or meetings) by drafting and circulating minutes for review and approval by all participants. The records of the meeting(s) can be archived in the one-stop shop to facilitate future safety assessment. The instructions for using the one-stop shop for an application for a single safety certificate apply also for a pre-engagement request (see Annex for more information).



Any pre-engagement is subject to charges (see section 3.5) and follows the standard communication rules (see section 6.4). The documents provided by the applicant and those developed during the pre-engagement stage are archived in the one-stop shop including, where relevant, the records of coordination activities.

Once the applicant requests pre-engagement the choice of the safety certification body becomes binding until:

- ▶ The application for a single safety certificate has been submitted by the applicant; or
- ▶ The applicant has requested to terminate the pre-engagement. In such a case the applicant can request new pre-engagement, selecting another safety certification body.

The pre-engagement stage must be closed, at the request of the applicant or when agreed by relevant parties, before the application for a single safety certificate is submitted.

6.1.2. 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. The notification sent to the applicant also includes information about the start date of the assessment against which milestones and deadlines will be monitored.

6.1.3. Initial screen

The initial screen ensures that the documentary evidence submitted by the applicant is sufficient, relevant and consistent for the detailed assessment to begin. The authorities for the area of operation each consult the application file as relevant, to:

- ▶ Determine whether the application is structured and internally cross-referenced so as to permit assessment to be effective and properly recorded;

6. The safety assessment

- ▶ Identify whether evidence is provided against the applicable requirements; and
- ▶ Ascertain the current status of the corrective action plan (or plans) put in place by the applicant to resolve any major non-compliance and any other area of concern identified during supervision activities since the previous assessment. For an application for the renewal or update of an existing single safety certificate this should include any residual concerns from the previous assessment, as appropriate.

Within the first month following the receipt of the application, the authorities involved in the safety assessment each check as relevant that:

- ▶ The applicant has provided the information which is required by the legislation;
- ▶ The application contains sufficient evidence, is structured and internally cross-referenced (e.g. the SMS manual contains signposts to other procedures and rules) to permit assessment to be effective and properly recorded; and
- ▶ The language of the application is of sufficient quality to permit the application file to be assessed.

The requirements that apply will differ according to whether it is a first, renewal or update application. For a **first application**, all the requirements set out in Annex I of the CSMs on SMS (including the relevant requirements in the TSI OPE) and the requirements laid down in the relevant national rules will apply. For **renewal and update applications**, the applicable requirements may vary from one case to another and, while the authorities involved in the safety assessment may make an initial judgement as to whether evidence for the correct requirements has been provided, this may not be fully evident until the detailed assessment is under way.

The national safety authority also checks that the documentary evidence provided by the applicant for the concerned area of operation is clearly identified and it takes into account any exclusions from having a single safety certificate applicable to its Member State in accordance with Article 2.3 of Directive (EU) 2016/798.

If any of the required information is not provided or if the application contains insufficient evidence or if the evidence is not presented clearly enough, including the quality of the language used, the applicant will be asked for the missing details or for clarifications through the issue log. If the quality of the language is so poor that it is not possible to understand the application at a level that allows the safety assessment, any necessary translation may be undertaken if this is possible within the timeframe. If the translation cannot be undertaken during the 1-month timeframe either the timeframe for the initial screen assessment can be extended or the application can be rejected.

Under Article 10 (1), (2) and (3) of the Railway Safety Directive (EU) 2016/798 it is clear that a new applicant for a single safety certificate must have a reasonable plan for conducting railway operations within a relatively short period after the granting of that single safety certificate. This is because they must have a safety management system which controls risks and be compliant with TSI's and other legislation in force. This means that they are able to supply information to the assessment body on the rolling stock that will be used the area and type of operation, the competence of staff and so on. The safety assessment process is not simply a paper exercise it must have a basis in reality. A safety certification body receiving

an application for a single safety certificate which does not contain enough information to properly assess whether the SMS of the applicant is capable of controlling its risks because it is incomplete or it does not relate to real activities should be prepared to reject the application and advise the applicant to reapply when they have a realistic prospect of starting operations.

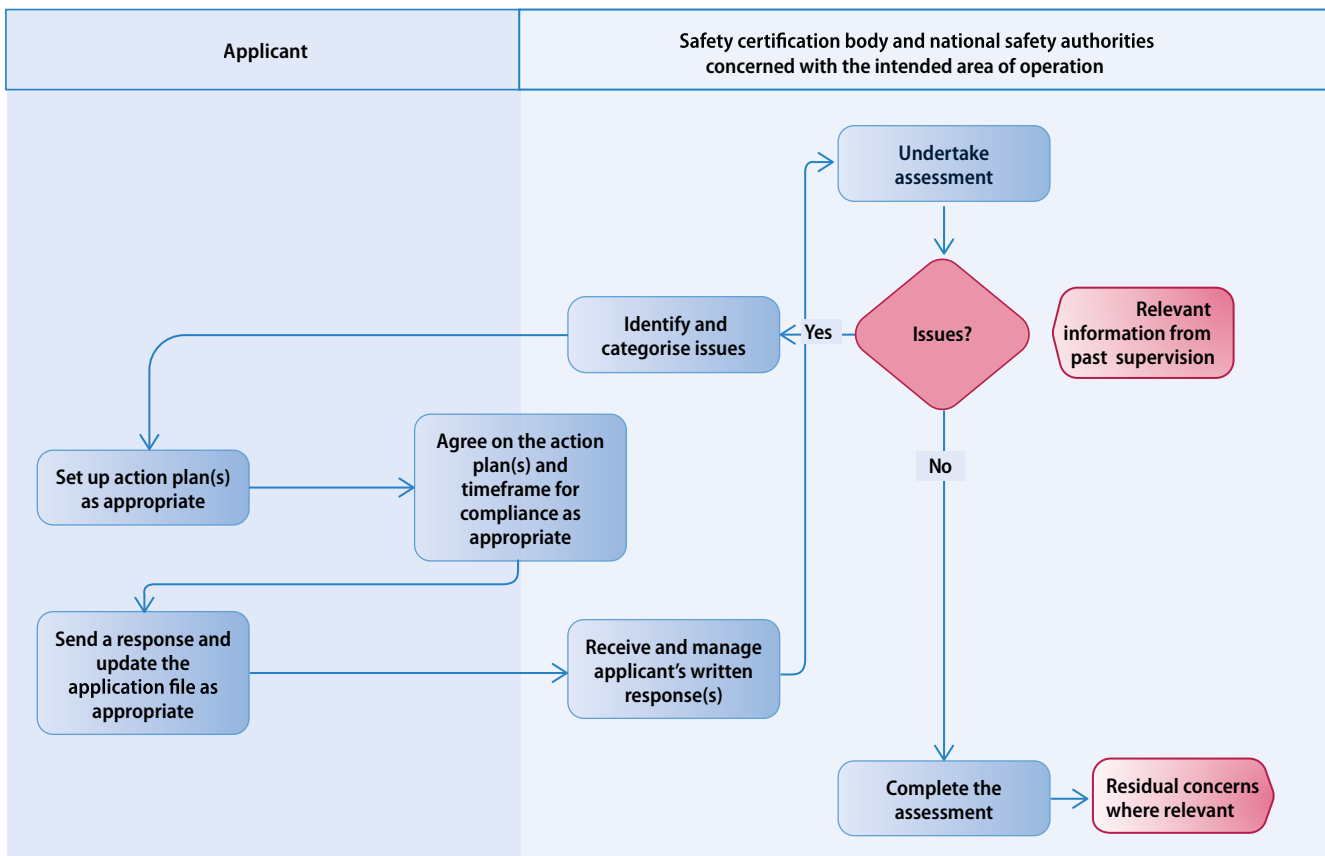
The safety certification body takes the final decision over the completeness, relevance and consistency of the application file and notifies the applicant of its decision through the one-stop shop.

6.1.4. Detailed assessment

The detailed assessment starts after a positive decision on the completeness, relevance and consistency of the application. Each authority proceeds for its own part to the detailed assessment of the application file. In the course of this stage, each authority:

- ▶ Analyses the results of past supervision collected during the initial screen (when applicable);
- ▶ Carries out the assessment of the evidence submitted by the applicant;
- ▶ Issues its opinion over the issuing of the single safety certificate.

Figure 4: The detailed assessment



6. The safety assessment

Based on the information collected during the previous stages, the authorities involved in the safety assessment define the scope of the assessment and decide whether issues have to be further investigated during on-site audits or inspections (see also section 6.6).

In the case of an update or renewal application (see also section 8), the authorities are required to have a targeted and proportionate approach to re-assessment.

During the course of the assessment, similarly to the initial screen stage, authorities involved in the safety assessment should promptly coordinate discussion of:

- ▶ Any issues (e.g. instance of non-compliance) and the need to request for further information;
- ▶ The outstanding issues identified during previous supervision;
- ▶ The contingency measures in case it will take a longer time to reach a final decision than the expected period.

When concluding such activities, the authorities involved in the safety assessment decide who will address each individual issue with the applicant.

6.1.5. Decision-making and closing of the assessment

The safety certification body is responsible for the decision to issue the single safety certificate or not. The decision consists of a cover letter, the assessment report and, where appropriate, the single safety certificate. It is recorded in the one-stop-shop and notified electronically to the applicant. The applicant can also download it from the one-stop shop, using the library functions.

If the decision is a refusal, the applicant may request that the safety certification body review its decision (see also section 7.1.2). If still not satisfied, the applicant may appeal (see section 7.1.3) to the competent authority, either a national appeal body (if the national safety authority is the safety certification body) or the Board of Appeal (if the Agency is the safety certification body). The applicant is obliged to request a review before it can appeal against the decision of the safety certification body.

The applicant may also decide to request a judicial review (see section 7.1.4).

The safety certification body completes the administrative closure of the assessment by ensuring that all documentation and records are reviewed, organised and archived in the one-stop shop.

6.2. Timeframe for the safety assessment

In accordance with Article 6 of Commission Implementing Regulation (EU) 2018/763, the timeframe for completing the safety assessment is managed as follows:

- ▶ A **1-month period** for checking the completeness of the application file (see also section 6.1.3). This period starts on the date of receipt of the application file. Where the national safety authority acts as the safety certification body, this date corresponds to the first

working day in the Member State concerned following the acknowledgement of receipt of the application file. Where the Agency acts as the safety certification body, this date corresponds to the first working day common to the safety certification body and the national safety authorities for the area of operation following the acknowledgement of receipt of the application file. By the end of this period the safety certification body has to either inform the applicant that the file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof;

- ▶ A **4-month period** to complete the detailed assessment of the application file (see also section 6.1.4), which begins with the notification of completeness of the application file and ends with the notification of the decision for issuing the single safety certificate to the applicant.

With a view to reducing the complexity, length and cost of the certification procedure whenever possible, the safety certification body is encouraged to complete the assessment process before these deadlines.



During the safety assessment different authorities may ask for additional information and clarification, each for its respective part of the assessment, always specifying the content of the request and a timeframe for the response. If the request for information or clarification has the potential to affect the work of other authorities, the different authorities are invited to coordinate in order to avoid duplicating the same request to the applicant. This does not, in general, extend the timeframe for the assessment unless major deficiencies/non-conformities or multiple minor deficiencies/ non-conformities are identified that prevent all or part of the assessment from continuing.

Any decision to extend the timeframe of the assessment is taken by the safety certification body in coordination with the different national safety authorities concerned with the area of operation, and agreed with the applicant. The extended timeframe includes both the period necessary for the applicant to provide the requested information and the period necessary for the relevant authorities to check if the newly provided information satisfies the request. If the response is not satisfactory, the safety certification body may further extend the timeframe of the assessment or propose the rejection of the application.

In the case where the Agency disagrees with the national safety authority(ies) concerned with the area of operation with regard to the results and outcome of their assessment (see also section 7.1.1), the timeframe of the assessment can also be extended for the following periods:

- ▶ the period of cooperation with a view to agreeing on a mutually acceptable assessment (i.e. up to 1 month);
- ▶ the period when the matter is referred to the Agency's Board of Appeal for arbitration (i.e. up to 1 month).

If the matter has been referred by the national safety authority(ies) to the Agency's Board of Appeal for arbitration, the time allotted to the Agency to take its final decision, based on the conclusions of the Board of Appeal, is part of the timeframe for the safety assessment.

If the end date of the assessment is such that a decision cannot be taken before the expiry date of the current single safety certificate or the planned start date of any new rail transport operation (e.g. due to delayed submission of an application file by an applicant or agreed extension of the timeframe of the assessment), the authorities involved in the safety assessment together with the applicant may apply contingency measures (see section 6.3).

6.3. Contingency measures

The different authorities may consider adopting contingency measures to address possible concerns regarding the prescribed timeframe for the assessment, in particular if it is felt that the single safety certificate cannot be granted on time (e.g. before the planned start date of a new rail transport operation). In such cases, a way to resolve the problem may be sought by the authority or authorities through mitigating measures, e.g. increasing the number of staff assigned to the application or issuing a single safety certificate with restrictions or conditions of use.

If a single safety certificate cannot be issued on time because the applicant has not submitted all requested information, the authorities should discuss the different options together with the applicant, for example to reject the application or to issue a single safety certificate with restrictions or conditions of use. The latter may relate to:

- ▶ The validity period of the certificate, under the condition that a shorter period is necessary to ensure the effective control of risks affecting the safety of railway operations;
- ▶ The type of operation – for example a single safety certificate excluding the transport of dangerous goods;
- ▶ The area of operation – for example a single safety certificate excluding a part of the intended area of operation.

Moreover, contingency measures might be necessary when a safety certificate is likely to expire before a renewal process can be completed due to the late submission of the application file. The authorities concerned, following partial assessment and information collected from past supervision may issue a certificate with a limited validity period and other restrictions or conditions of use (if applicable). This should allow an appropriate timeframe for the detailed assessment and, upon completion of this process, should allow the issuing of a single safety certificate for five years

6.4. Communication arrangements

Meetings (face to face or tele/video conference) or any kind of coordination activities involving the applicant may be planned at the request of any party (i.e. the authority or authorities or the applicant). The necessity for a meeting is discussed with the other parties, in order to determine whether any of these parties should also attend. When such a meeting is to be organised, the party requesting the meeting communicates all relevant details to the others, e.g. the meeting venue, date, agenda, contributions needed from each party etc. Records of meetings or any other coordination activities are made by the requester, with copies sent to all participants and uploaded in the one-stop shop.

In the case where the area of operation is not limited to one Member State, each authority involved in the safety assessment can request additional information from the applicant, each for their respective part of the assessment. The safety certification body should manage the coordination of requests addressed to the applicant (for supplementary information, meetings etc.) to avoid the authorities duplicating these requests. The applicant provides its response to the request in due course, through the one-stop shop. If the applicant does not provide the requested information in the required timeframe, an alert is sent to it and to the requester.

Coordination between parties involved in the safety assessment process is normally done in a mutually agreed language.

The decision of the safety certification body and the reasons for it are always made available in the language of the applicant (i.e. an official language of the Union chosen for the application file).

The above principles apply to all types of oral and written communication including all reports relevant for the safety assessment and other reports produced following a visit, inspection or audit (see also section 6.6).

6.5. Management of issues

6.5.1 Use of the issue log

The authorities involved in the safety assessment have to determine whether the applicable requirements (see section 5) are met. During the course of the safety assessment process, the assessors may raise issues during both the initial screen stage and the detailed assessment stage. All issues categorised as one of the four types specified below are recorded in the **issue log** of the one-stop shop to facilitate the communication and exchange of information between the different parties.

If all or part 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. This should be 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 timeframe it can discuss it with the concerned authority, which in turn can decide to adapt the timeframe for the expected response in the issue log.

To be satisfactory the written responses of the applicant 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 with an explanation of how this 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 the associated 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.

6. The safety assessment

Similarly, the applicant may propose measures to resolve issues and timescales for their implementation. If the concerned authority does not agree with the proposed measures and/or timescales it is invited to contact the applicant promptly to resolve the issue. The agreed resolution of the issue should be recorded in the issue log.

6.5.2. Categorisation of issues

Article 12 of Commission Implementing Regulation (EU) 2018/763 identifies four types of issues:

Type 1 corresponds to a query. In this case, the applicant is requested to provide additional information to clarify some aspects of the application file.

In this case the applicant may be required to supply information to clarify a particular matter of concern. For example, the organogram submitted by the applicant appears to show responsibilities for safety related matters to align in a certain way. However, the supporting explanatory text appears to show a different alignment, demonstrating a lack of clarity of safety responsibilities.

Type 2 corresponds to an observation or remark that is left to the judgement of the applicant.

For example, the assessor has noticed in the application file that there are some inconsistencies between referenced standards of the company. These discrepancies relate to different standards applied by different departments of the company. They do not have safety implications but do need to be resolved by the applicant.

Type 3 corresponds to a minor non-compliance or residual concern. The assessor raising the issue agrees with the applicant whether the resolution of the issue can be postponed until after the issue of the single safety certificate. In this case, the applicant is expected to resolve the matter before the next application for renewal or update. Before issuing the single safety certificate, it should be agreed among the authorities involved in the safety assessment which of them will follow-up these issues during its supervision activities. Type 3 issues that are not closed before the issuing of the single safety certificate will be transferred into the issue log for re-evaluation during the next renewal/update application.

A 'type 3' categorisation means that the issue identified will be noted with an expectation that it will be resolved by the applicant during the supervision activities after the granting of the single safety certificate. When multiple issues have been categorised as "type 3", an authority may decide to refrain from issuing the single safety certificate until these are resolved. The residual status is updated in the issue log accordingly by the assessor (i.e. s/he classifies the issue as "residual concern deferred for supervision"). Residual concerns may be closed by the safety certification body at the next renewal/update application by taking into account the information provided by the national safety authority.

For example, the assessor observes that an applicant states that it has set up a monitoring process in accordance with Regulation (EU) 1078/2012 but s/he finds evidence that the process has been accepted by only four out of five contractors. The applicant confirms that it still awaits final confirmation from the fifth, which will be responsible for non-safety-related tasks such as cleaning trains. In that case the assessor can accept the assurance of the applicant that the information will be provided and reclassify the issue as a residual concern to be confirmed later.

Type 4 corresponds to a major non-compliance where the point raised by the absence of information or the lack of clarity of such information is so important that the application cannot be accepted as it stands and a single safety certificate cannot be issued unless the issue is closed.

For example, an applicant submits an application where it has provided some evidence that a process for planning changes is in place. The analysis of the submitted information shows that there is no mention of Regulation (EU) 402/2013 as part of its risk management process. As there is a legal requirement to use this Regulation where appropriate, this is a major deficiency in the application file that must be corrected before the issue of the single safety certificate.

In general 'Type 4' issues will be those where the applicant has not demonstrated in its application file that it is complying with EU or national law, or there is evidence from the supporting documentation that it may not be. One possible solution for the resolution of such issues might be to impose restrictions or conditions of use in the single safety certificate. This option is appropriate if the restrictions or conditions of use can be clearly defined and do not affect other parts of the SMS. For example, an organisation may specify that it intends to operate both passenger and freight operations but provides no evidence that is able to control the risks related to its freight operations. In that case the applicant could have its single safety certificate restricted only to passenger operations.

Based on the information provided by the applicant, the authority may adapt the residual status of the issue as follows:

- (a) *'Issue pending' if the evidence provided by the applicant is not satisfactory and additional information is still required;*
- (b) *'Residual concern(s) for supervision' if the matter does not have direct consequences on the safety performance of the railway undertaking and so can be deferred for supervision; or*
- (c) *'Issue closed out' if a suitable response has been provided by the applicant and no residual matter of concern remains.*

Where a response to a 'Type 1' or 'Type 4' issue is received the assessor, being the issue owner, scrutinises the response and reclassifies the issue to reflect that the matter has been either satisfactorily dealt with or not. In the latter case the assessor provides its decision and the reasons for it in the issue log and requests additional information as appropriate.

6. The safety assessment

The assessor indicates why compliance is not achieved but it is then for the applicant to identify how it will achieve compliance and to agree with the assessor a timescale for doing so. If the timescale extends beyond the expected date of certification then further judgement is needed about whether the issue pending is a blocking point for issuing the single safety certificate.

If the applicant does not provide the requested information, or if the supplementary information provided by the applicant is not satisfactory, the timeframe of the assessment may be extended or an application can be rejected. Rejecting an application is 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 re-submission of the application.



6.6. Audits, inspections or visits

The authority or authorities involved in the safety assessment are empowered to conduct audits, inspections or visits at the site(s) of the applicant.

For the purposes of this guide:

- ▶ **Audit** means the structured intervention where the railway undertaking is examined against a particular safety management standard or against a particular audit protocol. Audits can be performed either off-site or on-site, using various techniques such as document review, interviews or sampling;
- ▶ **Inspection** means the use of an authorised and competent staff member of the safety certification body or relevant national safety authority, as appropriate, to examine a particular and limited aspect of the activity of a railway undertaking. Inspection should be for the purpose of establishing compliance with the SMS requirements and the notified national rules, or for verifying that what has been said or recorded in documents supporting the safety management system actually happens in practice. An inspection in the sense intended here both verifies that the process is in place and examines how well it works. It does not mean the 'tick-box' verification of the presence of certain documents or equipment, because this can only tell the Inspector that something is present not that it is being used in practice.
- ▶ **Visits** to the site of the applicant, other than those performed for the purpose of an inspection or an audit, are short notice interventions to specific parts of the site of the railway undertaking with the aim of observing the correct implementation of an SMS procedure.

The purpose of such audits, inspections or visits on the site of the applicant is 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. The authorities may decide to plan an audit, inspection or visit depending on the quality of the file under assessment, especially in the case of new applications where there are no records of previous supervision activities. However, these audits, inspections or visits to the site of the applicant do not replace the continuous supervision carried out by the national safety authority and are not intended to duplicate it.

6.7. Links between assessment and supervision

Assessment and subsequent supervision have a close relationship where the results of the assessment inform the national safety authority supervision and, in turn, the outcomes of the national safety authority supervision inform the re-assessment before the renewal or the update of the single safety certificate.

Issues identified during the assessment can be deferred for later supervision unless they concern major non-compliances that would prevent the issue of the single safety certificate (i.e. 'type 4' issues or multiple 'type 3' issues) and on condition that their follow-up is agreed by the competent national safety authority.

Supervision helps determine how effectively the SMS works, which can serve as input for the re-assessment of the application before the renewal or update of the single safety certificate. More detailed information can be found in the *Supervision guide*.

7. Arbitration, review, appeal and judicial review

7.1. Arbitration

Arbitration only applies in cases where the Agency acts as safety certification body, as referred to in Article 10(7) of Directive (EU) 2016/798.

During the course of the safety assessment, before taking its decision over the issue of the single safety certificate, the Agency may disagree with the assessment undertaken by one or more national safety authorities.

When the Agency disagrees with the negative assessment of one or more national safety authorities and no mutually acceptable assessment can be agreed on, the relevant national safety authority (or authorities) may refer the matter to the Agency's Board of Appeal. In such a case the Agency suspends its decision until the arbitration procedure is completed. Therefore, the time elapsed between the request for arbitration and the decision of the Board of Appeal is not considered part of the safety assessment timescale.

The applicant is informed through the one-stop shop about the extension of the timeframe of the assessment due to the arbitration procedure.

Where the Board of Appeal agrees with the Agency, the latter will take a decision and grant a single safety certificate without delay. Where the Board of Appeal agrees with the national safety authority the Agency will grant a single safety certificate without delay, with an area of operation excluding the parts of the network that received a negative assessment.

7.2. Review

The review process applies both to the Agency and to the national safety authority acting as safety certification body, as referred to in Article 10(12) of Directive (EU) 2016/798.

In cases where the safety certification body refuses the issue of a single safety certificate, or issues a single safety certificate with restrictions or conditions of use other than the ones identified by the applicant in its application form, the applicant may request the review of the decision within one month of the date of its notification. This request is submitted by the applicant through the one-stop shop.

The applicant justifies its request for review and includes a list of issues that, in its view, have not been properly considered during the safety assessment. In doing this the applicant should note that new supplementary evidence that has been developed after the notification of the decision will be disregarded by the safety certification body. If the applicant wants new evidence to be considered and assessed, this can be done only in the context of a new application.

When reviewing the case the safety certification body acts within the framework of its internal rules of procedure to ensure the impartiality of the process including, as far as reasonably practicable, the use of assessors that have not been involved in the first assessment. The review process follows the structure of the safety assessment process but is, however, limited to those issues that were the basis for the negative decision at the first assessment. In addition, the authorities involved will not perform any audit, inspection or visit to the site(s) of the applicant in relation to the list of issues included in the request for review.

The decision of the safety certification body to confirm or reverse its first decision is communicated to all parties involved in the safety assessment, including the applicant, through the one-stop shop within two months from the date of receipt of the request for review. Where the negative decision is reversed within the review process, the safety certification body issues a new single safety certificate without delay. The reviewed certificate is the same type of certificate (new/amended/renewed) as the original one subject to the review process. The original certificate is invalidated in the ERADIS database. If the negative decision of the safety certification body is confirmed, the applicant may bring an appeal before either:

- ▶ the Board of Appeal, for applications for which the Agency has been selected as a safety certification body – see also section 7.1.3; or
- ▶ the national appeal body in accordance with the relevant national procedure, for applications for which the national safety authority acts as safety certification body.

7.3. Appeal



After a request for review and in cases where the negative decision is confirmed, the applicant may still appeal against the decision of the safety certification body, as referred to in Article 10(12) of Directive (EU) 2016/798.

According to Article 59 of the Agency Regulation (EU) 2016/796, natural or legal persons may also appeal against a decision that is of direct and individual concern to them, even though the decision is addressed to another person (i.e. the applicant in the present case).

In the case where the national safety authority is the safety certification body, the appeal process is described in the application guide of the national safety authority.

In the case where the Agency is the safety certification body, the following appeal process applies.

The applicant files its appeal to the Board of Appeal. The Agency decides whether or not to suspend the application of its decision and notify accordingly all authorities involved in the safety assessment and the applicant, through the one-stop shop. The Board of Appeal decides within 3 months after the appeal has been filed whether to grant or refuse that appeal. The decision of the Board on Appeal on the appeal is also recorded in the one-stop shop.

Where the Board of Appeal finds that the grounds for appeal are well founded, it remits the case to the Agency. The Agency, in coordination with the national safety authority (or authorities) concerned by the area of operation, reviews its decision following the recommendation(s) of the Board of Appeal. This process follows the internal rules of procedure of the Agency and ensures impartiality including, as far as possible, the use of assessor(s) that have not been involved in the first assessment. The decisions of the Board of Appeal are recorded in the one-stop shop.

Where the decision, subject to the appeal process either of the Board of Appeal or the national appeal body, is reversed the safety certification body issues the single safety certificate without delay and in any case not later than one month following the notification of findings by the Board of Appeal.

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*]. The fee for an appeal is determined in accordance with Commission Implementing Regulation (EU) 2018/764 on fees and charges.

7.4. Judicial Review

Decisions taken by the safety certification body are subject to judicial review.

In the case where the Agency is the safety certification body, its decisions are subject to judicial review under Article 263 of the TFEU. An action for the annulment of an Agency decision or for failure to act within the applicable time limits may be brought before the Court of Justice of the EU only after the appeal procedure (see also section 7.1.3) has been exhausted, as stipulated in Article 63 of Regulation (EU) 2016/796.

In the case where the national safety authority is the safety certification body, its decisions are subject to judicial review under provisions of the national legislation. The procedure to request a judicial review is described in the application guide of the competent national safety authority.

8. Update and renewal of a single safety certificate

According to Article 10(13) and Article 10(14) of Directive (EU) 2016/798, the single safety certificate needs to be updated when the railway undertaking makes **substantial changes to the type or extent of the operation, or in case of extension of the area of operation**. The holder of a single safety certificate has to notify the safety certification body without delay whenever it proposes to make such changes. The changes can be of technical, operational or organisational nature.

An updated single safety certificate may be required when there are substantial changes in the safety regulatory framework in accordance with Article 10(15) of Directive (EU) 2016/798.



A single safety certificate might also need to be updated when the conditions under which it was issued have changed without any impact on the type, extent or area of operation.

A renewal of a single safety certificate is necessary for those railway undertakings who already have a valid single safety certificate and wish to continue their railway operations after the expiration of their current single safety certificate.

The safety certification body may bring to the attention of the applicant that its single safety certificate needs to be updated or renewed. It is good practice that this is done at least six months before the expiry of any existing safety certificate. The actual application for an update or renewal of a single safety certificate should not be on the initiative of the safety certification body but an action by the railway undertaking.

When applying for an update or renewal, the railway undertaking must hold a valid single safety certificate (or valid Part A and related Part B safety certificates) for the area of operation to be covered by the single safety certificate.

8.1. Assessment of the need to update a single safety certificate

It can be summarised that:

- (a) *the railway undertaking establishes and uses an SMS to ensure the control of all risks associated with its activities, including the safe management of changes. As part of the SMS, the railway undertaking also monitors the correct application and the effectiveness of the SMS arrangements, including the risk control measures;*
- (b) *the safety certification body is responsible for granting the safety certificate. After the granting of the single safety certificate, the national safety authority undertakes supervision to oversee the continued compliance of the railway undertaking's SMS with its legal obligations;*

8. Update and renewal of a single safety certificate

- (c) *Article 10 (13), Article (14) and Article 10(15) of Directive (EU) 2016/798 set out the conditions for the update of the safety certificate;*
- (d) *Annex II of Implementing Regulation (EU) 2018/763 requires the holder of the single safety certificate to inform the safety certification body of all substantial changes in the type, extent or area of operation.*

The railway undertaking submits an application through the one-stop shop for the update of its valid single safety certificate.

The applicant describes the proposed changes, including all the measures taken to mitigate the risks, which involve a change to its SMS arrangements. The changes made to the documentation may be indicated in a number of ways, using a table or highlighted text for example, but need to be clearly identified in the tables cross-referencing the documentary evidence with the legal requirements, that are annexed to the application file.

In the case of an update of the single safety certificate, the scope of the SMS re-assessment should in any case be proportionate to the level of risk introduced by the change(s) and should focus on the relevant areas.

In order to identify the relevant requirements upon which to assess the application for the update the authorities involved in the safety assessment consider the changes made to the documentary evidence that was submitted in the previous application and take into account the results of past supervision activities.

However, this does not preclude the authorities involved in the safety assessment from making, in certain cases, a complete re-assessment of the application file. For example, a complete re-assessment might be performed if the applicant does not provide sufficient information about the changes made to its SMS, or the application is made during a transition phase between one regulatory regime and another, or if there are significant matters of concern raised during previous supervision activities.



8.1.1. Type and extent of operation

The terms “type” and “extent” of operation are defined in Article 3 of Directive (EU) 2016/798 as follows:



- (a) **Type of operation** is characterised by:
 1. *passenger transport, including and excluding high-speed services;*
 2. *freight transport, including and excluding dangerous goods services, and*
 3. *shunting services only;*
- (b) **Extent of operation** is characterised by :
 1. *the number of passenger and/or volume of goods, and*
 2. *the estimated size of the railway undertaking in terms of employees working in the railway sector (micro, small, medium sized, large enterprise).*

Furthermore, regarding the type of operation, it has been acknowledged that other types of services may exist, such as operations in privately owned sidings, testing of vehicles etc. These additional types of services should be identified in the application form.

8.1.2. Extension of the area of operation

In the case of an extension of the area of operation, the railway undertaking makes the necessary changes to the evidence submitted in the previous application. This should cover the relevant requirements laid down in the notified national rules for the new area of operation.

When such an application for an update is submitted, even if the change affects only one authority, all authorities involved in the previous safety assessment will be notified accordingly.

8.1.3. Change of safety regulatory framework

Any substantial change in the safety regulatory framework (e.g. a new EU Regulation, a national regulation including new or revised notified national safety rules) has to be identified and managed by the railway undertaking through its SMS processes (e.g. compliance with legal and other safety requirements, change management process). The railway undertaking is then responsible for complying with the new or revised legal requirements. As part of its duties the national safety authority has to promote the safety regulatory framework. Therefore the national safety authority is expected to give support as appropriate to the railway undertaking for it to understand the content of the changes made to the safety regulatory framework.

8.1.4. Change to the conditions under which the single safety certificate was issued

As a general rule, the railway undertaking is responsible for engaging with the safety certification body when it plans a change to the conditions under which the single safety certificate was issued. This covers a variety of changes that the railway undertaking might plan. These may range from simple administrative ones to substantial operational ones (e.g. a change to the SMS procedures that has been identified as significant according to Regulation (EU) 402/2013).

The administrative changes are limited to changes in basic information in the single safety certificate (e.g. legal denomination, registration number and VAT number) without any impact on the type, extent or area of operation. For such administrative changes a simplified process for updating the single safety certificate may be applicable and the safety certification body decides, at the request of the railway undertaking, whether the single safety certificate needs to be updated.

Before taking the decision to apply such a simplified process, the safety certification body is encouraged to check that the notified change does not hide organisational changes which may affect the operation of the train (e.g. change of the name or registration data due to restructuring of the company, or merging of two different companies with reallocation of safety related tasks and responsibilities).

8.1.5. Examples of changes that could require the update of a safety certificate

Any substantial change made to the type or extent of the operation requires the update of the single safety certificate. In addition, any extension of the area of operation requires the update of the single safety certificate. However, the provisions in the SMS of the railway undertaking should be laid down in such a way that they are valid for the intended area of operation (e.g. infrastructures of different Member States).

In most of the cases any change made to the type of operation as specified in the certificate requires an update.

Changes made to the extent of operation require more reflection as this information is not directly reflected in the certificate and is more dependent on changes in company resources and its business performance.

All changes recognised as “substantial” lead to a re-assessment and an update of the certificate. This applies whether the change concerned arises from business developments within a company or from the taking over of another company’s operation.

For example, if a railway undertaking delivering passenger transport intends also to operate freight transport, after either merging with or acquiring another company, this should be considered as a “substantial change” in the “type and extent” of the service delivered by the railway undertaking and the single safety certificate should then be updated.

If the change does not affect the type or extent of the operation, or if the need for update of the single safety certificate is not obvious, the question of new or increased risk for the railway company’s operation may need to be considered as a parameter. In addition it should be questioned whether the change can be managed safely through the safety management system of the railway undertaking. As already mentioned, the scope of the SMS re-assessment must in any case be proportionate to the level of risk introduced by the change(s) and to the nature and significance of the change(s):

- (a) **Example 1:** *a change of legal denomination of the railway company requires the update of the certificate. However, the change of legal denomination of the railway company should not require the re-assessment of the railway undertaking’s SMS as it is an act of an administrative nature and there is no change to their operation;*
- (b) **Example 2:** *changes to a lower risk (e.g. change from passenger transport including high-speed services to passenger transport excluding high-speed services) is generally an administrative exercise with only minimal checks on the implications for the railway company SMS;*
- (c) **Example 3:** *changes to a higher risk (e.g. from freight transport excluding dangerous good services to freight transport including dangerous good services) should be regarded as a substantial change. This should require the assessment of the change under the SMS provisions and the update of the single safety certificate;*

- (d) *Changes that potentially create higher risks for the operation could be regarded as substantial ones and might therefore require the assessment of the change under the SMS provisions and possibly the update of the single safety certificate:*
1. **Example 4:** introduction of “Driver Only Operation” within a company previously operating with on board guard or staff assisting the driver with platform operations should be regarded as a substantial change;
 2. **Example 5:** freight operators which go into the passenger market, either running charters or ancillary services for passenger train operators, should be regarded as a substantial change;
- (e) **Example 6:** *taking into account that the internal restructuring of a railway company could have adverse effects on its SMS arrangements and that the existing processes and procedures of the SMS need to be redesigned or new ones to be developed, such a change could be considered as a substantial change that requires a deeper and more complete re-assessment of the railway undertaking’s SMS.*
- (f) **Example 7:** *the change of route could be a substantial change if an operation is proposed for a line or a part of the network on which there was previously no operation by that railway undertaking (except for temporary diversions) and this new route would increase the risk (e.g. exposure to a new risk for that railway undertaking). An example of such a change is starting operation through a sub-surface station or lengthy tunnels;*
- (g) **Example 8:** *an increase in the frequency of service could increase the risk for the railway undertaking, e.g. potential risks arising from congestion. Such changes should not be considered as substantial ones; they can be managed safely through the SMS of the railway undertaking:*
1. *The SMS has processes and procedures in place to keep risks under control and to take appropriate preventive or corrective actions in case of detection of non-compliances during the monitoring of the operation by the railway undertaking;*
 2. *The railway undertaking notifies changes to the national safety authorities, so that the national safety authority is able to identify the additional supervisory tasks to be included in its strategy and plan for the supervision of the railway undertaking;*
- (h) **Example 9:** *similarly, an increase in “route passenger-km per year” or “freight tonne-km per year” might increase the risk as the scale of the operation is affected. However, such changes and the associated risks can also be managed safely through the railway undertaking’s SMS. The national safety authority can verify how this is done during the supervision activities of the railway undertaking, taking into account the change management information notified by the railway undertaking.*

8.2. Renewal of a single safety certificate

A single safety certificate is renewed upon the request of the applicant before the expiry of its validity, to ensure continuity of certification. The applicant applies for the renewal of its valid single safety certificate through the one-stop shop (see also section 3.2).

8. Update and renewal of a single safety certificate

In the case of a renewal the authorities concerned with the area of operation follow a targeted and proportionate approach to re-assessment, checking the changes to the evidence submitted in the previous application and also considering the results of past supervision activities to identify the relevant requirements against which to assess the application for the renewal.

However, this does not preclude the authorities involved in the safety assessment from making, in certain cases, a complete re-assessment of the application file. For example, a complete re-assessment might be performed if the applicant does not provide sufficient information for the changes made to its SMS, or if there are significant matters of concern raised during previous supervision activities.



An application for renewal of a single safety certificate may be merged with an application for an update of the same single safety certificate. For example, an applicant having a single safety certificate that covers an area of operation in two Member States.



9. 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. Such a restriction or revocation happens when the safety certification body is notified by a national safety authority that, following its supervision activities, the holder of the single safety certificate no longer satisfies the conditions under which it has been certified.

If the national safety authority identifies a serious safety risk it may decide to take proportionate enforcement action. For instance, the national safety authority may decide to suspend the rail operations of the railway undertaking. Based on this decision the safety certification body evaluates the need to update the single safety certificate with restrictions or, in the last resort, to revoke it. Where the Agency acts as safety certification body coordination takes place between the authorities for the area of operation before taking a decision.

The railway undertaking whose single safety certificate has been restricted or revoked has the right to appeal against the decision of the safety certification body (see section 7.1.3).

Any request from the national safety authority to restrict a single safety certificate is managed in the one-stop shop. If the decision is to restrict the single safety certificate, the safety certification body issues a new single safety certificate including the restrictions or conditions of use.

Any request from the national safety authority to revoke a valid single safety certificate is managed directly in the ERADIS database in accordance with existing procedures.

ANNEX

Instructions for use with regard to the content of the application for a single safety certificate

When submitting an application for a single safety certificate or requesting pre-engagement, the applicant is requested to complete an application form.

The following table provides commentary on the application for a single safety certificate, as drawn up in Annex I of Implementing Regulation (EU) 2018/763 for easy reference and guidance, this table uses the same numbering as Annex I of the Implementing Regulation.

Table 1: Commentary on the application for a single safety certificate

Annex I of Implementing Regulation (EU) 2018/763.	Commentary
1.1-1.3	<p>The applicant selects the relevant type of application as follow:</p> <ul style="list-style-type: none"> ▶ 'New': if applying for the first time for a single safety certificate or if the previous single safety certificate has been revoked; ▶ 'Renewal': if the previous valid (single) safety certificate is about to expire and its period of validity needs to be extended to ensure continuity of its rail operations; ▶ 'Update': if the type or extent of the operation is substantially altered, or substantial changes have been made to the safety regulatory framework, or if the conditions have changed under which the (single) safety certificate was issued.
1.2	<p>A single safety certificate shall be renewed upon application by the railway undertaking at intervals not exceeding five years, in accordance with Article 10(13) of Directive (EU) 2016/798.</p>
1.4	<p>When applying for a renewal or an update, specify or select the EIN(s) of the previous (single) safety certificate (e.g. a single safety certificate or a Part A safety certificate) in relation to which the application is being submitted to the safety certification body.</p> <p>The EIN(s) of the previous safety certificate are used to invalidate the corresponding certificate(s) in the ERADIS database. In case of doubt, it is advised that the applicant contacts the safety certification body before submitting its application.</p>
2.1-2.2	<p>When applying for passenger services (as a part of or as the whole of an application), it has to be specified, by ticking the appropriate box, whether the operations include or exclude high-speed services: only one option may be selected. However the services referred to by selecting option 2.1 or 2.2 include any other type of passenger operation (i.e. regional, short, medium, long distance etc.) as well as of any other service necessary to carry out the passenger services applied for (shunting operations etc.). For the definition of high-speed services, refer to Annex I of Directive (EU) 2016/797.</p>
2.3-2.4	<p>When applying for freight services (as a part of or as the whole of an application), it has to be specified, by ticking the appropriate box, whether the operations include or exclude transport of dangerous goods: only one option may be selected. However the services referred to by selecting option 2.3 or 2.4 include any other type of freight transport not explicitly mentioned as well as of any other service necessary to carry out the freight services applied for (shunting operations etc.).</p> <p>The applicant should also be aware that if they select 'dangerous goods' they will need to provide evidence of compliance with the Transport of Dangerous Goods by Rail Regulations.</p>

2.5	This box shall be selected if the applicant intends to carry out only shunting services without performing passenger or freight transport. The applicant has to specify whether the intended services include or exclude shunting wagons of dangerous goods. This box may also be selected in conjunction with box 2.6 if the applicant intends to carry out other types of operations.
2.6	<p>If the applicant intends to carry out other types of operations it has to specify what these services are, for example:</p> <ul style="list-style-type: none"> ▶ Operation of vehicles on privately owned sidings, when not excluded from the scope of its safety management system in accordance with Article 2(3) of Directive (EU) 2016/798; ▶ Tests of running behaviour of vehicles and/or stationary tests of vehicles; ▶ Operation of vehicles for infrastructure maintenance activities. ▶ Any training centres to be recognised in accordance with Article 5 of Commission Decision 2011/765/EU (see section 4 for more details). <p>Any particular national requirements relating to the type(s) of operations can also be added in this field.</p>
3.1	When referring to the services applied for, it is necessary to specify the date on which operational service is intended to begin or, in case of a renewed or updated certificate, the date on which the certificate is intended to become effective and replace the previous one.
3.2	The applicant has to select the Member State for the intended area of operation.
3.3	<p>The applicant defines its intended area of operation, which may cover the whole railway network of one or more Member States or only a defined part thereof. In the case where the applicant intends to operate only on a defined part of a network it has to either:</p> <ul style="list-style-type: none"> ▶ describe the area of operation it intends to operate as “from point A to point B” (e.g. Paris – Brussels), or ▶ list the networks on which it intends to operate, or ▶ specify clearly all the lines, including all relevant diversionary lines, where services are intended to be operated. <p>Applicants must refer to lines using the denomination/names given in the ‘Network Statement’ (refer to Article 3 and Annex IV of Directive 2012/34/EU). It is also advised to include the type of signalling systems intended to be used and their geographical extent.</p> <p>Please note that when an applicant decides to apply for a detailed area of operation, any change to this area will require an update of the single safety certificate. The way the area of operation is defined is a business decision for the applicant.</p>
3.4	If the applicant operates in neighbouring Member State(s) to station(s) that are close to the border it shall identify them clearly.
4.1-4.2	The applicant may select the Agency or the national safety authority as safety certification body (or issuing authority) if the area of operation is limited to one Member State. The applicant shall select the Agency if the area of operation is more than one Member State.
5.1	Only Legal Denomination is to be included.
5.2	The acronym of the railway undertaking can be indicated here (optional).
5.3-5.7	<p>Each applicant shall provide the necessary information to allow the safety certification body to contact the railway undertaking.</p> <ul style="list-style-type: none"> ▶ A telephone number should be for the railway undertaking’s switchboard, where applicable, and not for the person in charge of the assessment process. ▶ Telephone numbers, and fax numbers where applicable, should include the country code. ▶ The e-mail address should be for the general mail box of the railway undertaking. ▶ The railway undertaking contact information should indicate the general address, and avoid references to a specific person as this information may be entered in points 6.1 to 6.6. Specification of the website (5.7) is not compulsory.

5.8-5.9	If several registration numbers are attributed under national law to the applicant railway undertaking, the one-stop shop form permits the entry of both the VAT number (5.9) and a second registration number (5.8) (e.g. trade register).
5.10	Information in addition to that clearly requested in the other fields can be added if necessary.
6.1-6.8	Throughout the assessment process the contact person is the interface between the railway undertaking submitting its application for a single safety certificate and the safety certification body and relevant national safety authority (or authorities) as appropriate. The contact person provides support, assistance, information and clarifications where necessary, and is the reference point for the safety certification body and relevant national safety authority (or authorities) as appropriate. The contact person is authorised and empowered to represent the applicant organisation. Telephone numbers, and fax numbers where applicable, should include the country code.
7.1	This documented information shall be submitted when applying for a single safety certificate. If the application is for a renewal or an update of the single safety certificate then the changes made to the information submitted in the previous application shall be clearly identified in the different documents as applicable. The 'Summary of the Safety Management System (SMS)' is intended to be a document reviewing and underlining the main elements of the railway undertaking's SMS. It must detail and give supporting information to demonstrate the compliance of the SMS with the assessment criteria set out in Annex II of Commission Delegated Regulation (EU) 2018/763, cross-referencing more detailed documents where relevant. Clear reference should be made to the processes and documents where the Technical Specifications for Interoperability (TSIs) are applicable and implemented. To avoid duplication of work and to reduce the amount of information submitted, summary documentation should be provided in respect of elements that comply with TSIs and other EU applicable legislation.
7.2	A table mapping the main elements of the railway undertaking's SMS to the assessment criteria set out in Annex II of Commission Delegated Regulation (EU) 2018/763, providing evidence of compliance of the general SMS provisions with requirements from Article 9 of Directive (EU) 2016/798. Also an indication of where in the safety management system documentation the requirements of the applicable functional Technical Specification for Interoperability relating to the operation and traffic management subsystem are met.
8.1	The applicant shall submit documentation relating to the notified national rules applicable to the services intended to be operated with the requested certificate. The specific documentation relating to the rail transport operation on the network (or part of it) of each Member State in which the applicant intends to operate shall be part of separate attachments to the application form, as appropriate, in accordance with the language policy set by the national safety authority of the relevant Member State(s).
8.2	A table mapping the specific elements of the railway undertaking's SMS to the requirements laid down in the relevant notified national rules, providing evidence of compliance of the specific SMS provisions with the applicable requirements set out in the notified national rules
9.1	The current status of the action plan (or plans) established by the railway undertaking to resolve any major non-compliance and any other area of concern identified during supervision activities since the previous assessment;
9.2	The current status of the action plan (or plans) established by the railway undertaking to resolve residual concerns from previous assessments.



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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