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## Working Paper

*Agency proposal for the Commission Implementing Act on practical arrangements for safety certification as referred to in Article 10(10) of Directive (EU) 2016/798*

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### Document History

<i>Version</i>	<i>Date</i>	<i>Comments</i>
0.18	08/12/2016	Following external consultation and outcomes of discussions at workshop IV.
0.19	16/12/2016	Following internal review meeting.
1.0	20/12/2016	Final Agency proposal.

## Recitals

- (1) This Regulation provides the practical arrangements for issuing single safety certificates as referred to in Article 10(10) of Directive (EU) 2016/798, supplementing Commission Delegated Regulation (EU) No ...<sup>1</sup>. Where necessary, it identifies additional requirements with the aim of harmonising the approach to safety certification at Union level and fostering collaboration among all the parties involved in the certification process.
- (2) A fundamental objective of this Regulation is to reduce complexity, length and cost of the certification procedure.
- (3) These practical arrangements are to be supplemented by cooperation agreements, as referred to in Article 11(1) of Directive (EU) 2016/798. In the case of networks requiring specific expertise for geographical or historical reasons and where such networks are isolated from the rest of the Union rail system, as referred to in Article 11(2) of Directive (EU) 2016/798, cooperation arrangements may also include the possibility of contracting tasks to the relevant national safety authorities when this is necessary in order to ensure efficient and proportionate allocation of resources for certification.
- (4) Taking into account the experience gained in the preparation of these practical arrangements and the cooperation agreements referred to in Article 11(1) of Directive (EU) 2016/798, a coordination or pre-engagement with the applicant before the submittal of an application for a single safety certificate is recognised as good practice to facilitate the early contact and the development of the relationship between the involved parties in the certification process. Such coordination or pre-engagement should be performed before submitting an application for a single safety certificate with the aim of gaining familiarity with the applicant's safety management system, clarifying how the certification process will be conducted and how decision will be made and verifying that the applicant has received sufficient information to know what is expected of it.
- (5) In the case of those Member States whose rail networks have a track gauge that is different from that of the main rail network within the Union and share identical technical and operational requirements with neighbouring third countries, as referred to in Article 11(3) of Directive (EU) 2016/798, all the national safety authorities concerned in those Member States may conclude with the Agency, in addition to the cooperation agreements referred to in Article 76 of Regulation (EU) 2016/796, a multilateral agreement which should apply when the applicant requests the Agency to issue single safety certificates. The purpose of such multilateral agreement is to avoid any duplication of assessment and unnecessary costs to be borne by the applicant.
- (6) The Agency and national safety authorities are free to establish their own information management system consistent with the certification process, without prejudice to the practical arrangements set out in this Regulation and the cooperation agreements referred to in Article 11 of Directive (EU) 2016/798.
- (7) When the applicant intends to operate to station(s) in neighbouring Member State(s) with similar network characteristics and similar operating rules, when those stations are close to the border, it should have the possibility of choosing whether to submit its application for a single safety certificate, through the one-stop shop, to the Agency or to the national safety authority. In the case where the national safety authority is the safety certification body, it should consult the relevant national safety authority (or authorities) in accordance with Article 10(8) of Directive (EU) 2016/798.

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<sup>1</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

- (8) In the case where the Agency acts as safety certification body, the applicant should have the right to submit to the Agency its application file in any EU official language, without creating any obligation to translate it. During the course of the assessment, the national safety authority should have the right to submit to the Agency documents pertaining to the assessment in a language of its Member State, without creating any obligation to translate them.<sup>2</sup>

## General provisions

### Article 1

#### **Subject matter and scope**

1. The applicant shall apply the practical arrangements set out in this Regulation for submitting a new, renewal or update application for a single safety certificate through the one-stop shop.
2. The Agency and national safety authorities shall apply the practical arrangements set out in this Regulation for assessing a new, renewal or update application for a single safety certificate.
3. The safety certification body shall apply the practical arrangements set out in this Regulation when taking its decision over the issue of single safety certificates and coordinating with the relevant national safety authority (or authorities) when and where appropriate.

### Article 2

#### **Definitions**

For the purposes of this Regulation, the definitions of Article 3 of Commission Delegated Regulation (EU) No ../.<sup>3</sup> shall apply.

In addition, the following definitions shall apply:

‘certification process’ means the structured and auditable process for assessing conformity with the requirements for obtaining single safety certificates as referred to in Article 10(3), Article 10(4) and Article 10(5) of Directive (EU) 2016/798.

‘one-stop shop’ means a component of the information and communications system as referred to in Article 12 of Regulation (EU) 2016/796.

‘date of receipt of the application’ means the first working day following the submission of the application file, common to the safety certification body and the relevant national safety authority (or authorities) as appropriate.

### Article 3

#### **Responsibilities of the Agency and national safety authority**

1. The safety certification body shall be responsible for:
  - (a) the planning, implementation and monitoring of the assessment work it carries out;
  - (b) the assignment of the tasks to and the setting up of coordination arrangements between the relevant parties; and
  - (c) any single safety certificates it issues.

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<sup>2</sup> This recital will have to be revised by the EC, in coordination with the Agency, when drafting its Implementing Act in order to take into account the decision of the Agency Management Board on an Agency linguistic regime. It shall be removed when the Agency Management Board adopts a linguistic regime.

<sup>3</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

2. The safety certification body and the relevant national safety authority (or authorities) as appropriate shall apply the stages of the certification process as set out in Annex I of Commission Delegated Regulation (EU) No ../.<sup>4</sup> and fulfil their statutory tasks pursuant to Article 10 of Directive (EU) 2016/798.

In accordance with Article 4(2) of Commission Delegated Regulation (EU) No ../.<sup>5</sup>, in the case of single safety certificates issued by the Agency, the relevant national safety authority (or authorities) concerned by the area of operation shall coordinate or pre-engage with the applicant upon its request before the submission of the application for a single safety certificate.

3. For the purposes of issuing single safety certificates, the safety certification body and the relevant national safety authority (or authorities) as appropriate shall be responsible, each for their own part, for providing:

- (a) the details of the assessment, in accordance with Article 12, including a justification for the decisions taken during the assessment and the identification of any limitation or condition of use to be included in the single safety certificate; and
- (b) the outcome of the assessment, including summary conclusions and where appropriate, an opinion over the issue of the single safety certificate.

4. The Agency shall monitor the expiry dates of all valid single safety certificates with an area of operation in more than one Member State and share this information with the relevant national safety authorities where and when appropriate to establish the planning of their respective safety certification activities.

5. National safety authorities shall share with the Agency and the other relevant national safety authority (or authorities) all relevant information resulting from their statutory tasks that may have an impact on the planning of the certification process, in particular when the coordination between the Agency and relevant national safety authority (or authorities) is required.

6. The Agency shall publish and keep up to date an application guide, free of charge, describing and explaining where necessary the requirements set out in this Regulation and Commission Delegated Regulation (EU) No ../.<sup>6</sup>. This application guide shall indicate the documents which shall be supplied in the application for a single safety certificate in order to comply with the provisions of Article 10(3)(a) of Directive (EU) 2016/798. This application guide shall also include model templates to be developed by the Agency in cooperation with the national safety authorities with the aim of harmonising the approach to the exchange and recording of information through the one-stop shop.

7. The national safety authority shall publish and keep up to date an application guide, free of charge, describing and explaining the rules that are valid for the intended area of operation and the documents which shall be supplied in the application for a single safety certificate in order to comply with the provisions of Article 10(3)(b) and Article 10(8) of Directive (EU) 2016/798.

8. The Agency and the national safety authority shall have internal arrangements or procedure(s) for managing the issue of single safety certificates which conform with the provisions of this Regulation and Commission Delegated Regulation (EU) No ../.<sup>7</sup>, with a view to reducing administrative burdens and costs to the applicant.

9. Each single safety certificate shall be given a unique European Identification Number (EIN) of which the structure and content are defined and maintained by the Agency on its website.

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<sup>4</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

<sup>5</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

<sup>6</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

<sup>7</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

10. When the Agency acts as safety certification body and the applicant intends to operate to station(s) in neighbouring Member State(s) with similar network characteristics and similar operating rules, when those stations are close to the border, the Agency shall consult the relevant national safety authorities, taking into consideration any related cross-border agreement between these national safety authorities or their respective Member State.

#### *Article 4*

#### ***Responsibilities of the applicant***

1. Without prejudice to the timeframe allowed for the assessment set out in Article 6, the application for a single safety certificate, including its update or renewal, shall be formally submitted by the applicant through the single entry point of the one-stop shop sufficiently in advance before:

- (a) the planned start date of any new rail transport operation;
- (b) the planned start date of a rail transport operation under changing conditions, other than those laid down in the single safety certificate previously issued, following a substantial change made to the type, extent or area of operation; or
- (c) the expiry date of the current single safety certificate.

2. If an applicant requests coordination or pre-engagement as referred to in the second subparagraph of Article 3(2), it shall formally submit an application through the one-stop shop with at least the information listed in Annex I.1 to I.6.

3. When submitting a new application for a single safety certificate, the applicant shall provide the information listed in Annex I, including an indication of where the evidence against each CSM assessment criterion as set out in Annex II of Commission Delegated Regulation (EU) No ../.<sup>8</sup> and relevant national rules notified in accordance with Article 8 of Directive (EU) 2016/798 can be found in the submitted file.

4. The application for renewal or update shall include the information listed in Annex I, describe changes made since the current certificate was issued and indicate where the evidence against the relevant CSM assessment criterion (or criteria) and as appropriate national rules can be found in the submitted file.

5. When submitting its application for a single safety certificate, the applicant shall select the safety certification body in accordance with Article 10(5) and Article 10(8) of Directive (EU) 2016/798.

6. The selection of the safety certification body made by the applicant shall be binding until the safety assessment process is completed or terminated.

7. Whenever an extension of its area of operation to several Member States is required, the applicant shall submit an update application, in accordance with Article 4(1), Article 4(4) and Article 4(5).

#### *Article 5*

#### ***Language<sup>9</sup>***

1. Where the area of operation is limited to one Member State, the applicant shall submit its application file in an EU official language permitted by the safety certification body.

2. Where the area of operation involves more than one Member State, the applicant shall:

- (a) submit the part of the application file referred to in Article 10(3)(a) of Directive (EU) 2016/798 in one of the EU official languages; and

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<sup>8</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

<sup>9</sup> This article will have to be revised by the EC, in coordination with the Agency, when drafting its Implementing Act in order to take into account the decision of the Agency Management Board on an Agency linguistic regime. Paragraphs 5, 7 and 8 shall be removed when the Agency Management Board adopts a linguistic regime.

- (b) translate the part(s) of the application file referred to in Article 10(3)(b) of Directive (EU) 2016/798 in accordance with the language policy of the relevant national safety authority (or authorities), appropriate to the needs of the assessment.
3. The request for translation referred to in point (b) of paragraph 2 shall include the description or other demonstration of how the safety management arrangements address the requirements set out in Article 10(3)(b) of Directive (EU) 2016/798, which is necessary for the respective national safety authority to understand in order to assess compliance with the notified national rules.
4. The applicable language policy referred to in point (b) of paragraph 2 shall be defined in the application guide of the national safety authority as referred to in Article 3(7).
5. Any coordination between parties involved in the certification process shall use the English language for the exchange and recording of information in cases where the use of common language(s) cannot be accommodated. During coordination, any relevant documented information can be provided by the relevant national safety authority (or authorities) in English or in any other commonly agreed language(s).
6. The national safety authority (or authorities) shall provide the details and outcome of the assessment referred to in Article 3(3), in English and/or in any other commonly agreed language(s) referred to in paragraph 5.
7. If the area of operation is more than one Member State, the Agency shall provide the final results of the assessment in English or in any other commonly agreed language(s) referred to in paragraph 5.
8. Any single safety certificate to be issued by the Agency shall be in the language of the part of the application file referred to in Article 10(3)(a) of Directive (EU) 2016/798, in accordance with paragraph 1 and paragraph 2, and in any other language either used by the Agency to take its decision over the issue of the single safety certificate or requested by a national safety authority concerned by the area of operation where appropriate.

#### *Article 6*

#### ***Timeframe for the assessment***

1. The safety certification body and the relevant national safety authority (or authorities) as appropriate shall evaluate, each for their own part, the completeness of the application file according to the required documentary evidence listed in Annex I within one month following the date of receipt of the application. The safety certification body shall without undue delay inform the applicant accordingly.
2. If the applicant is informed that its file is complete, the final decision over the issue of the single safety certificate shall be taken no later than four months following the acknowledgement of the completeness of the application.
3. If the applicant is informed that its file is not complete, the final decision over the issue of the single safety certificate shall be taken no later than four months following the submission of the necessary information by the applicant unless the application is so fundamentally deficient that it has to be rejected thereby.

#### *Article 7*

#### ***Communication***

1. The safety certification body and the relevant national safety authority (or authorities) as appropriate shall use the one-stop shop to request for relevant information needed to complete its or their part of the assessment. The applicant shall respond to this request through the one-stop shop.
2. Without prejudice to paragraph 1, the Agency and the national safety authorities shall establish the applicable rules for communicating between themselves and with the applicant where appropriate, in particular how they shall receive, manage information on, and respond to relevant communications.
3. The Agency and the national safety authorities shall include the rules referred to in paragraph 2 in their respective application guide.

### *Article 8*

#### ***Period of validity of single safety certificates***

1. Single safety certificates shall be valid for a period of five years and renewed upon application by the applicant at intervals not exceeding five years.
2. The safety certification body may decide in coordination with the relevant national safety authority (or authorities) as appropriate to grant the single safety certificate for a period shorter than the period referred to in paragraph 1, giving reasons. In this case, the safety certification body shall demonstrate that a shorter period is necessary to ensure the effective control of risks affecting the safety of railway operations.

### *Article 9*

#### ***Information management***

1. The safety certification body and the relevant national safety authority (or authorities) as appropriate shall register in the one-stop shop the outcomes of all stages of the certification process, each for their respective part of the assessment as applicable, including the decision to issue or not the single safety certificate. The status of all stages of the certification process and the decision shall be communicated to the applicant through the one-stop shop.
2. Document control shall be exercised through the one-stop shop where shall be recorded all documents ensuring the traceability of decisions taken during the assessment.

### *Article 10*

#### ***Audits, inspections or visits under Article 10(5) Directive (EU) 2016/798***

1. Any audit, inspection or visit on the site(s) of the applicant shall be planned in order to collect additional evidence that could not be retrieved from the documentary review of the application file and to get assurance that areas of significant concern identified during assessment, not previously addressed by supervision as applicable, have been adequately addressed by the applicant. The objectives and scope of these audits, inspection or visits shall be agreed among the different authorities, including the role assigned to them where appropriate.
2. When arranging an audit, inspection or visit on the site(s) of the applicant, the safety certification body and/or the relevant national safety authority (or authorities) as appropriate shall obtain details of whom will represent the applicant and the site safety rules and procedures it (or they) has (or have) to conform to.
3. A report shall be produced following an audit, inspection or visit on the site(s) of the applicant, identifying issues raised at the assessment stage that can be closed by means of evidence provided during the audit, inspection or visit. This report may also include any additional instance of non-compliance or deficiency that has to be resolved by the applicant within an agreed timeframe. Copies of this report shall be sent to all participants and recorded in the one-stop shop.
4. The timeframe for the audits, inspections or visits, including the exchange of information referred to in paragraph 2, shall be agreed with all interested parties.
5. The Agency or the national safety authority undertaking an audit or inspection shall have internal procedures setting out the framework for delivering it.

### *Article 11*

#### ***Coordination between the Agency, acting as safety certification body, and national safety authority (or authorities)***

1. The Agency shall coordinate with the relevant national safety authority (or authorities) at the different stages of the certification process in order to discuss any issues pertaining to them, including any instance of non-compliance and request for supplementary information when the latter has an impact on the timeframe of the assessment or has the potential to affect the work of other bodies, and agree on the way forward.

2. In conclusion of such coordination activities, the safety certification body and the relevant national safety authority (or authorities) as appropriate shall take, each for their own part, the decision to inform the applicant of any instance of non-compliance and/or request for supplementary information.
3. The national safety authority (or authorities) of the Member State(s) concerned by the area of operation shall in its coordination activities with the Agency exchange relevant information from previous supervision, in accordance with Article 6 of Commission Delegated Regulation (EU) No ..../..<sup>10</sup> and cooperation agreements referred to in Article 11 of Directive (EU) 2016/798, where applicable.
4. Before taking its decision over the issue of the single safety certificate, the Agency and relevant national safety authority (or authorities) shall:
  - (a) discuss the outcome of their respective assessment;
  - (b) agree on residual concern(s) to be deferred for later supervision, in accordance with Article 6 and Annex I of Commission Delegated Regulation (EU) No ..../..<sup>11</sup>; and
  - (c) agree on limitation(s) or condition(s) of use to be included in the single safety certificate.
5. The national safety authorities shall agree which national safety authority (or authorities) should follow up the completion of the relevant action plan(s) set by the applicant to address the residual concern(s) referred to in point (b) of paragraph 4. To that end, the national safety authorities shall coordinate where appropriate, in accordance with the arrangements referred to in Article 9(1) of Commission Delegated Regulation (EU) No ..../..<sup>12</sup>, and inform the Agency about their agreement and the outcome of their related supervision activities.
6. Records of coordination activities shall be taken by the Agency and maintained in the one-stop shop in accordance with Article 9.

#### Article 12

#### **Categorisation of issues**

1. During the course of their assessment, without prejudice to Article 7(1), the safety certification body and the relevant national safety authority (or authorities) as appropriate may identify different type of issues on the application file which should be categorised as follow:
  - (a) 'Type 1' that requires a response from the applicant for the understanding of the application file;
  - (b) 'Type 2' that may lead to an amendment of the application file or a minor action expected of the applicant. The action to take is left to the judgement of the applicant and does not prevent the granting of the single safety certificate;
  - (c) 'Type 3' that requires a specific action to be taken by the applicant, for which its completion can be postponed after the granting of the single safety certificate. Any action to resolve an issue is proposed by the applicant and is to be agreed with the party that identified the issue; or
  - (d) 'Type 4' that requires an amendment of the application file or a specific action to be taken by the applicant. The single safety certificate shall not be delivered unless the issue is closed out or limitations or conditions of use are identified to address the issue. Any action to resolve an issue is proposed by the applicant and is to be agreed with the party that identified the issue.
2. Following the applicant's formal response, the safety certification body or the national safety authority may re-evaluate its comments, re-classify them when relevant and provide for each of the comments raised the residual status as follow:

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<sup>10</sup> Common Safety Method for supervision by national safety authorities after issuing a single safety certificate or safety authorisation.

<sup>11</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

<sup>12</sup> Common Safety Method for supervision by national safety authorities after issuing a single safety certificate or safety authorisation.

- (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 applicant's response has been provided and no residual matter of concern remains.

#### *Article 13*

#### ***Arbitration under Article 10(7) of Directive (EU) 2016/798 and Article 12(4)(b) of Regulation (EU) 2016/796***

In the case where the Agency acts as safety certification body, the certification process may be suspended by the Agency in consultation with relevant national safety authority (or authorities) during the cooperation needed to reach a mutually acceptable assessment and where applicable, until the Board of Appeal takes a decision.

#### *Article 14*

#### ***Review under Article 10(12) of Directive (EU) 2016/798***

1. In cases where the decision of the safety certification body is for refusal or contains limitations or conditions of use other than those defined in the application, the applicant may request the review of the decision within one month from the date of its receipt. This request shall be submitted by the applicant through the one-stop shop.
2. The request for review shall be duly substantiated and include a list of issues that, in the view of the applicant, have not been properly considered during the certification process.
3. Any supplementary information which has been developed and filed after the completion of the certification process shall not be admissible as evidence.
4. During the review process, the safety certification body in coordination with the relevant national safety authority (or authorities) as appropriate shall ensure independence and impartiality of the review process, including, to the extent practicable, the use of experts that have not been assigned to the assessment under review.
5. The review process shall target the issues justifying the negative decision of the safety certification body in accordance with the applicant's request.
6. When the Agency acts as safety certification body, it shall decide to reverse its decision subject to review in coordination with the relevant national safety authority (or authorities).
7. The safety certification body shall confirm or reverse its first decision within two months from the date of receipt of the request for review. This decision shall be communicated to the relevant parties through the one-stop shop.

#### *Article 15*

#### ***Transitional provisions***

1. The Part A and related Part B safety certificates issued in accordance with Directive 2004/49/EC and Commission Regulation (EU) No 1158/2010 shall cease to be valid after the earliest expiry date of any one of those safety certificates.
2. In cases referred to in paragraph 1, an application for a single safety certificate shall be submitted to the safety certification body in accordance with Directive (EU) 2016/798, Commission Delegated Regulation (EU) No ..../..<sup>13</sup> and this Regulation.

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<sup>13</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

If the area of operation is not limited to one Member State, the single safety certificate referred to in the first subparagraph shall exclude the network(s) in the Member State(s) that has (have) notified the Agency or the Commission in accordance with Article 33(2) of Directive (EU) 2016/798 where applicable. The national safety authority of that Member State shall issue Part B safety certificates from 16 June 2019 with a validity period not extending beyond that of the single safety certificate.

*Article 16*

***Repeal***

Regulation (EC) No 653/2007 is repealed with effect from 16 June 2019 in respect of areas of operation in the Member States that have not notified the Agency or the Commission in accordance with Article 33(2) of Directive (EU) 2016/798. It is fully repealed with effect from 16 June 2020.

*Article 17*

***Entry into force***

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 16 June 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at

For the Commission

The President

## Annex I: Content of the application for a single safety certificate

(M) means required information.

(O) means optional information.

### 1. Type of application: (M)

- 1.1 New
- 1.2 Renewal
- 1.3 Update
- 1.4 EIN of the previous certificate (in case of renewal or update application only)

### 2. Type of operation requested (select one or more): (M)<sup>14</sup>

- 2.1 Passenger transport including high-speed services
- 2.2 Passenger transport excluding high-speed services
- 2.3 Freight transport including dangerous goods services
- 2.4 Freight transport excluding dangerous goods services
- 2.5 Shunting only
- 2.6 Other (specify)

### 3. Rail transport operations:

- 3.1 Expected date of starting services / operations (O)
- 3.2 Member State(s) concerned by the intended area of operation (M)
- 3.3 Definition of the area of operation (for the concerned network(s)) (M)<sup>15</sup>
- 3.4 Station(s) in neighbouring Member State(s) (in the cases provided for by Article 3(10) of this Regulation and Article 10(8) of Directive (EU) 2016/798) (M)

### 4. Issuing authority: (M)

- 4.1 The Agency
- 4.2 The national safety authority (in the cases provided for by Article 10(8) of Directive (EU) 2016/798)

### 5. Applicant's information:

- 5.1 Legal denomination (M)
- 5.2 Applicant's name (M)
- 5.3 Acronym (O)
- 5.4 Complete postal address (M)

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<sup>14</sup> For each Member State concerned by the intended area of operation.

<sup>15</sup> For each Member State concerned by the intended area of operation.

- 5.5 Phone (M)
- 5.6 Fax (O)
- 5.7 E-mail (M)
- 5.8 Website (O)
- 5.9 National registration number (M)
- 5.10 VAT number (O)
- 5.11 Other relevant information (O)

**6. Contact person information:**

- 6.1 First name (M)
- 6.2 Surname (M)
- 6.3 Title or function (M)
- 6.4 Complete postal address (M)
- 6.5 Phone (M)
- 6.6 Fax (O)
- 6.7 E-mail (M)
- 6.8 Language(s) spoken (M)

**Annexes: (M)****7. Documents submitted for the safety management system part of the assessment:**

- 7.1 Summary of the Safety Management System (SMS) and other documented information demonstrating compliance with the requirements set out in Article 9 and Article 10(3)(a) of Directive (EU) 2016/798 and with the assessment criteria set out in Annex II of Commission Delegated Regulation (EU) No ../..<sup>16</sup>
- 7.2 Information cross-referencing the safety management system (see 7.1) against Annex II of Commission Delegated Regulation (EU) No ../..<sup>17</sup>

**8. Documents submitted for the national part(s) (for each Member State covered by the intended area of operation) of the assessment:**

- 8.1 Description or other demonstration of how the safety management arrangements address the operating rules of the railway network and rules concerning requirements in respect of staff executing safety-critical tasks, in order to demonstrate compliance with the requirements set out in Article 10(3)(b) of Directive (EU) 2016/798

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<sup>16</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

<sup>17</sup> Common Safety Method for assessing conformity with the requirements for obtaining railway single safety certificates.

8.2 Information cross-referencing the safety management system (see 7.1) against the requirements laid down in the relevant national rules (see 8.1)