

Law on Interoperability within the Railway System

I. GENERAL PROVISIONS

Subject of regulation Article 1

- (1) This law regulates the conditions which the railway system of the Republic of Macedonia should fulfill due to safe and uninterrupted movement of the rail vehicles on the level of the trans-European conventional railway system, through compatibility of the certain sub-systems based on technical, operational and managing conditions which should be fulfilled in order to fulfill the essential requirements in accordance with the Law.
- (2) The conditions referred to in paragraph (1) of this Article apply to: design, construction, reconstruction, renewal, placing in service, operation and maintenance of the parts of the railway system, as well as the professional qualifications, health and safety conditions of the staff included in the operation and maintenance of the railway system.
- (3) The conditions referred to in paragraph (2) of this Article are applied on the railway tracks which are not part of the trans-European railway system.
- (4) The conditions for providing of interoperability are not applied on networks which are functionally separated from the railway network and railway vehicles, and are intended exclusively for local, urban and suburban transport services, of the railway undertakings in private property and the railway vehicles which are used on such infrastructure that exist solely for use by the owner for its freight operations and the infrastructure and railway vehicles reserved for local, historical or touristic use.

Definitions Article 2

Certain terms of this Law have the following meaning:

1. Trans-European railway system - Trans-European conventional and high-speed rail system.
2. Interoperability - the ability of the railway system to allow the safe and uninterrupted movement of trains which accomplish the required levels needed for performance of the railway lines. This ability depends on all the regulatory, technical and operational conditions which must be met in order to satisfy the essential requirements.
3. Railway vehicle is the vehicle that runs on its own wheels on railway lines, with or without traction. The vehicle is composed of one or more structural and functional subsystems or parts of such subsystems.
4. Railway network is the overall railway infrastructure which is managed by its infrastructure manager, needed to ensure safe and condition for operation of the railway system.
5. Subsystem is the division of the railway system for which essential requirements must be laid down and which may be structural or functional.
6. Interoperability constituents is any elementary component, group of components, sub-assembly, or complete assembly of equipment incorporated or intended for incorporation into the sub-system of which the interoperability of the railway system depends, directly or indirectly. The term "constituent" covers material and non-material assets, as, for example, software applications.
7. Essential requirements are all the conditions which must be met by the railway system, sub-systems and the interoperability constituents including the interfaces.
8. European specification is a common, technical specification, European technical approval or national standard transposing to the European standard.
9. Technical specifications for interoperability are specification which includes each sub-system or part of the sub-system in order to meet the essential requirements and ensures interoperability of the railway system.
10. Notified body is a legal entity responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising of the EC procedure for verification of the sub-systems.

11. Basic parameters are the regulatory, technical or operational conditions which are critical to interoperability and are specified within the relevant technical specifications for interoperability.
12. Specific case is part of the railway system for which needs special provisions within the technical specifications for interoperability, temporary or definite, due to geographical, topographical or urban environment constrains or those affecting compatibility with the existing system. Here are included, in particular, the railway lines and networks, isolated from the rest of the railway network, the loading gauge, the track gauge or the space between the railway tracks and the railway vehicles which are strictly intended for local, regional or historic use, as well as railway vehicles which originating from or destined for third countries.
13. Upgrading is a major modification work on the sub-system or part of the sub-system, which improves the overall performance of the sub-system.
14. Renewal is a major substitution work on a subsystem or part of a subsystem, which does not change the overall performance of the subsystem.
15. Existing railway system is a structure composed of railway lines and fixed installations of the existing railway system, as well as the railway vehicles of all categories and origin traveling on that infrastructure.
16. Substitution in the framework of maintenance is the replacement of components by parts identical function and performance in the framework of the preventive or corrective maintenance.
17. Placing in service means all the operations by which the subsystem or the railway vehicles is put into its design operating state.
18. Contracting entity means a public or private legal entity that orders the design and/or construction, renewal or upgrading of a subsystem, which may be a railway undertaking, infrastructure manager or keeper or the concession holder responsible for carrying out the project.
19. Keeper is a legal entity who owns or uses a railway vehicle and is registered at the National vehicle register.
20. Project at an advanced stage of development is the project who's planning/ construction stage has reached a point where the change of the technical specifications would be unacceptable. This obstacle can be legal, contracting, economic, financial, social or environmental and must be duly substantiated.
21. Harmonised standard are the European standards adopted by the European Standardisation bodies, and are accepted by the Institute for standardisation.
22. Safety authority is the Directorate for safety in the railway system, as an authority within the Ministry of transport and communications to which the tasks related to the safety of the railway are given, to provide unified safety regime for specialized cross boarder infrastructure in accordance with the law.
23. Type of vehicle is defining the basic project characteristics of a railway vehicle as covered by a single type- examination certificate, in accordance with a written procedure.
24. Series is the number of identical railway vehicles of a design type.
25. Entity in charge of maintenance is a legal entity in charge of maintenance of a railway vehicle and registered as such in the National vehicle register.

II. TRANS-EUROPEAN CONVENTIONAL RAILWAY SYSTEM

Railway network

Article 3

- (1) The railway system in the Republic of Macedonia is part of the Trans-European conventional railway system.
- (2) The railway network in the Republic of Macedonia, as part of the Trans-European conventional railway system is divided in the following categories:
 - railway lines intended for passenger services
 - railway lines intended for mixed traffic (passengers and freight)
 - railway lines specially designed or upgraded for freight services
 - passengers' hubs
 - freight's hubs, including the intermodal terminals and
 - railway lines connecting the above mentioned elements.

(3) The railway network includes traffic management, tracking and navigation system, technical installations for data processing and telecommunications intended for long –distance services and freight services in order to guarantee the safe and harmonized operation of the network, as well as efficient traffic management.

Railway vehicles

Article 4

(1) The railway system in the Republic of Macedonia, as part of the Trans-European conventional railway system comprised all the railway vehicles (further referred to as: vehicles) which can be used in the traffic of the overall railway network in the Republic of Macedonia, including:

- self-propelling diesel or electric trains
- diesel or electric locomotives
- passenger carriages
- freight wagon, including vehicles designed to carry lorries
- vehicles for maintenance of the railway infrastructure.

(2) The vehicles referred to in paragraph 1 of this Article can be divided into:

- vehicles for international use
- vehicles for national use

Subsystems

Article 5

(1) The conventional railway system in the Republic of Macedonia is divided into: structural and functional subsystem.

(2) The structural subsystem includes the following areas:

- railway infrastructure
- energy
- control-command and signalling
- vehicles.

(3) The functional subsystem includes the following areas:

- traffic operation and management
- maintenance
- telematics applications for passenger and freight services.

(4) For each subsystem or part of a subsystem, the European Railway Agency (ERA) suggests a list of constituents and aspects related to interoperability, which is being prepared in the period of drawing up of the relevant technical specifications.

(5) The subsystems include:

- for railway infrastructure: track, points, engineering structures (bridges, tunnels etc.), associated station infrastructure (platforms, access zones, including the needs of persons with reduced mobility etc.), safety equipment and equipment for protection at work.
- for energy: electrification system, including the overhead lines and on-board parts of the electric consumption measuring equipment in the vehicles.
- for control-command and signaling: equipment necessary to ensure safety and to command and control movements of trains authorized to travel on the network.
- for operational and traffic management: procedures and related equipment which enables coherent operation of different structural subsystems, during a normal and decreased operation, including training, train driving,

traffic planning and management, as well as professional qualifications which may be required for carrying out cross-boarder services.

- telematic applications which are composed of two elements:

(a) applications for passengers services, including system providing passengers with information before and during the journey, system for reservation and payment, luggage management and management with the connections between trains and with other modes of transport;

(b) applications for freight services, including the information system (real time of monitoring the trains and freight), marshalling and allocation system, system for reservation, system for payment and invoicing, management with the connection with other modes of transport and issuing of electronic accompanying documents.

- for rolling stock: structure, command and control system for the whole train equipment, current – collection devices traction and energy conversion unit, braking, coupling and running gear (bogies, axles, etc.) and suspension, doors, man-machine interfaces (driver, on-board staff, and passengers, including the needs of persons with reduced mobility), passive or active safety devices and requisites for the health of passengers and on-board staff.

- for maintenance: procedures, associate equipment, logistic centers for maintenance work and reserves allowing mandatory corrective and preventive maintenance to ensure the interoperability of the railway system and guarantee the performance required.

Compatibility of the railway system

Article 6

(1) Each subsystem, the interoperability constituents, the interfaces and procedures, as well as the conditions which demand acquiring full compatibility of the railway system should be fully interoperable.

(2) In case when the interoperability constituents, including interfaces, compliance with the essential requirements according to this and other Law, in that case may require the use of individual European specifications drawn up for that purpose.

(3) The quality of the railway services depends on the compatibility between the characteristics of the network and those of the vehicles', where the performance levels, safety, quality of services and cost depend upon that compatibility.

Essential requirements

Article 7

(1) The railway system, the subsystems and the interoperability constituents, including interfaces shall meet the relevant essential requirements. The essential requirements may be general and specific for each subsystem.

(2) The technical specifications for interoperability which are necessary to complete European specifications or other standards, must not conflict with the essential requirements.

(3) The essential requirements referred to in paragraph 1 of this Article are issued by the Minister of transport and communications.

III. TECHNICAL SPECIFICATIONS FOR INTEROPERABILITY

Content of the technical specifications for interoperability

Article 8

(1) Each of the subsystems shall be covered by one technical specification. In case of need, one subsystem may be covered by several technical specifications and one technical specification may cover several subsystems.

(2) When placing in service of a new subsystem, upgrading or renewal, it should be in accordance with the technical specifications which are in force; this compliance shall be permanently maintained while each subsystem is in use.

(3) The technical specification:

a) indicate its intended scope for which the technical specification is indented in relation to the network or the vehicles in accordance with Article 3 and 4 of this Law, as well as for the subsystems or part of the subsystems referred to in Article 5 of this Law;

b) lay down essential requirements for each related particular subsystem and its interfaces visa-a-vis other subsystems;

c) establish the functional and technical specifications to be met by the subsystem and its interfaces visa-a-vis other subsystems. If needed be, these specifications may vary according to the use of the subsystem;

d) determine the interoperability constituents and interfaces which must be covered by European specifications, including the European standards, which are necessary to achieve the interoperability within the rail system;

e) state which procedure are to be used in order to assess the conformity or the suitability for use of the interoperability constituents, on one hand or the EC verification of the subsystems on the other hand;

f) indicate the strategy for implementing the technical specification i.e. to specify the stages which have to be completed in order to make gradual transition from the existing situation to the final situation, in which compliance with the TSI's shall be a norm;

g) indicate the professional qualifications, health and safety conditions for the staff concern at the work required for the operation and maintenance of the subsystems, as well as for the implementation of the technical specifications.

(4) Each technical specification shall be drawn up on the bases of an existing subsystem, and at the same time indicate a target subsystem that maybe obtained gradually within a reasonable time scale and by gradual adoption of the technical specifications and compliance will help gradually to achieve the interoperability of the rail system.

(5) The technical specification provides compatibility of the existing rail system.

(6) When compatibility of a certain technical specification with the existing rail system is not provided, in that case, a specific case for that technical specification is adopted - for the network and for the vehicles, by paying special attention to the loading gauge, track gauge or space between the track and vehicles. For each specific case, the TSI's shall stipulate the implementing rules of the elements of TSI's indicated in paragraph 3, items (c) to (g) of this Article.

(7) If certain technical aspects which corresponding to the essential requirements cannot be explicitly covered in a TSI, they shall be clearly identified in an annex to the TSI as an open points. In that case, Article 16, paragraph 2, 3, 4 and 5 of this Law are applied.

(8) The technical specifications shall not be an impediment concerning the use of rail infrastructures for movement of the vehicles which are not covered by TSI's, and they are in accordance with other applicable international standards which are accepted by Republic of Macedonia.

(9) The TSI's can refer to the European or the international standards, specification or technical documents published by the European railway agency. In that case, these standards and specifications (or relevant parts) or technical documents shall be regarded as annexes to the relevant technical specification and shall become mandatory from the moment when the technical specification is applicable.

(10) In the absence of standards or specifications or technical documents referred to in paragraph 9 of this Article and pending their development, reference may be made to other clearly identified normative documents which are easily accessible and in the public domain.

(11) The list of the normative documents referred to in paragraph 10 of this Article is being maintained and published on the website of the Directorate for safety in the rail system.

(12) The technical specifications are published in the Official Journal of the European Union, and in Republic of Macedonia they are accepted.

(13) The list of adopted technical specifications is maintained and published on their website by the Directorate for safety in the rail system.

Derogation of the enforcement of the technical specifications

Article 9

(1) The enforcement of the technical specifications is obligatory.

(2) Notwithstanding paragraph 1 of this Article, the application of one or more technical specifications may not apply in accordance with the following cases:

- a) for a proposed new subsystem, for renewal or upgrading of an existing subsystem or for any element referred to in Article 1, paragraph 2 of this Law which are in advanced stage development or when the procedure for concluding a contract is ongoing, and the technical specification is published,
- b) for a project concerning renewal or upgrading of the existing subsystem where the loading gauge, track gauge or the space between the track or the electrification voltage is not compatible to those for the existing subsystem;
- c) for any proposed renewal, extension or upgrading of the existing subsystem, when the application of the relevant technical specifications would compromise the economic viability of the project and/or the compatibility of the rail system;
- d) Where following an accident or a natural disaster, the conditions for rapid restoration of the network do not allow, economically or technically, a full or partial appliance of the relevant technical specifications;
- e) for vehicles which come or go to other countries whose track gauge is different from the gauge of the main railway network in the Republic of Macedonia;

(3) When submitting a request for derogation, the following documents are enclosed:

- a) A formal letter proposing the derogation;
- b) A file, as an attachment to the letter, containing:
 - description of the work, goods and services which are subject of derogation, by specifying the key dates, geographic location, operational and technical area;
 - precise reference to the technical specifications (or parts of it) for which the derogation is requested;
 - precise reference to and details of the alternative provisions which will be applied;
 - justification of derogations, if the project is in advanced stage of development;
 - justification of the derogation, including the main reasons from technical, economic, commercial, operational and/or administrative nature;
 - any other information for justification of the request for derogation;
 - description of the measures proposed to take in order to promote the final interoperability of the project. In case of a smaller derogation, a description is not required.

(4) The documentation referred to in paragraph 3 of this Article must be delivered in written form, as well as in electronic form to the Directorate for safety in the rail system (further referred to as: Directorate).

(5) In the case referred to in paragraph 2, item (a) of this Article, within one year of the entering into force of each technical specification, the contracting entity delivers a list of projects which are implemented and are in the advanced stage of development to the Directorate.

(6) In cases referred to in paragraph 2, item (a) and (d) of this Article, the Directorate shall check that the file is in conformity and shall inform the contracting entity of the results of its analysis. If necessary, a recommendation shall be drawn up concerning the specifications and the Directorate may apply the alternative provision delivered within the file without delay.

(7) In cases referred to in paragraph 2, items (b), (d) and (f) of this Article, the Directorate shall decide whether to accept the request for derogation. In the case referred to in paragraph 2, item (b), the decision of the Directorate shall not cover the loading gauge and the track gauge. The Directorate shall give its decision within six months of the submission of the request with enclosed full documentation of the file. If a decision is not adopted, it is considered that the request shall be deemed to have been accepted. Until the reaching of a decision by the Directorate, in the case referred to in paragraph 2, item (f), the contracting entity in question may apply the alternative provision stated in the file.

(8) The Directorate informs the European Agency for railways for the results of the analysis and of the outcome of the procedure set out in paragraphs 4 and 5 of this Article.

IV. INTEROPERABILITY CONSTITUENTS

Placing on the market of interoperability constituents

Article 10

(1) The Directorate takes all the steps to ensure that the interoperability constituents:

- are placed on the market, only if they enable interoperability to be achieved within the rail system, and which meet the essential requirements;
- are used in their area of use and are suitably installed and maintained.

(2) The provisions referred to in paragraph 1 of this Article are not an obstacle for placing on the market of these constituents for other applications.

(3) The placing on the market of the interoperability constituents for use in the rail system may not be prohibited, restricted or hindered, if they are in accordance with this Law, and may not require checks which have been already carried out as part of the procedure to receive an EC declaration of conformity or suitability of use, which content is prescribed by the Minister of transport and communications.

Conformity or suitability for use

Article 11

(1) The interoperability constituents which bear the EC declaration of conformity or suitability for use are considered to comply with the essential requirements.

(2) The interoperability constituents shall be subject to the procedure for assessing conformity or suitability for use indicated in the relevant technical specification and shall be accompanied by the corresponding certificate.

(3) An interoperability constituents shall be considered that meets the essential requirements if it is in accordance with the conditions lay down by the relevant technical specification or the relevant European specifications.

(4) When subsystems are placed in services, and the relevant technical specification enters into force, spare parts may be installed for that subsystem without being a subject of the procedure referred to in paragraph 2 of this Article.

(5) The technical specifications which are already in force may provide a transitional period of rail products which are already placed on the market, and are being used as interoperability constituents.

(6) The interoperability constituents referred to in the case of paragraph 5 of this Article shall satisfy the requirements of Article 10, paragraph 1 and 2 of this Law.

Procedure for EC Declaration of conformity or suitability for use

Article 12

(1) In order to establish the procedure for issuing the EC Declaration of conformity or suitability for use of interoperability constituents, the manufacturer or its authorized representative shall apply the provisions laid down by the relevant technical specifications.

(2) If the relevant technical specification so requires, the assessment of conformity or suitability for use of interoperability constituents shall be carried out by the Notified body where the manufacturer or its authorized representative has submitted the application.

(3) If the interoperability constituents are subject of other legal regulations which cover other aspects, the EC declaration of conformity or suitability for use shall state that the interoperability constituents also meet the other requirements determined by other legal regulations.

(4) If neither the manufacturer nor its authorized representative has met the obligations of paragraph 1 and 3 of this Article, shall be incumbent of any legal entities that place at the market the interoperability constituents. These obligations are applied for legal entities who assemble interoperability constituents or parts of interoperability constituents' identical components with different origin or who manufacture interoperability constituents for their own use.

(5) If the Directorate assess that the EC Declaration of conformity has been drawn up improperly, the manufacturer or its authorized representative shall be required to restore the interoperability constituents to a stage of conformity and to terminate the infringement under the conditions laid down by the Directorate.

(6) If nonconformity persists, in that case the Directorate shall take appropriate steps to restrict or prohibit the placing on the market of the interoperability constituents or to ensure that it is withdrawn from the market in accordance with the procedures referred to in Article 13 of this Law.

Noncompliance of the interoperability constituents with essential requirements

Article 13

(1) If it is being assessed that the interoperability constituents covered by the EC Declaration of conformity or suitability for use and placed on the market, which is being used for the given intention, does not fulfill the essential requirements, the Directorate takes the necessary steps to restrict field of application,

prohibit its use or withdrawn from the market, by stating the reasons for that decision, especially whether the incompliance is a result of:

- a) non-fulfillment of the essential requirements
- b) incorrect application of the European specifications
- c) inadequacy of the European specifications.

(2) If the interoperability constituents bearing the EC Declaration of conformity fail to comply, the appropriate measures are being undertaken against who so ever has drawn up the Declaration.

V. Subsystems

Procedure for placing in service

Article 14

- (1) The structural subsystems defined in Article 5, paragraph 2 and 3 of this Law may be placed in service only if they are designed, constructed, and installed in such a way as to meet the essential requirements for their integration within the rail system, and the following things are checked:
 - the technical compatibility of the structural subsystems to the rail system in which it is being integrated
 - the integration of the structural subsystem from the aspect of safety, in accordance with Article 4, paragraph 4 and 5 and Article 6 of the Law on safety in the railway system.
- (2) Before placing in service of the subsystems, a control is conducted for whether the same is in accordance with the provisions stated in the relevant technical specification from point of view of operation and maintenance of the subsystem by Directorate.
- (3) After the placing in service the check shall be carried out by the Directorate, as follows:
 - for railway infrastructure, in the context of granting and supervision of safety authorization in accordance with Article 22 of the Law on railway system and
 - for vehicles, in the context of granting and supervision of safety certificate in accordance with Article 19 of the Law on railway system.
- (4) When conducting the control referred to in paragraph 3 of this Article, the procedures for assessment and verification laid down in the relevant structural and functional technical specification shall be used.

Free movement of the subsystems

Article 15

The structural subsystems which compose the railway system and which fulfill the essential requirements must not be prohibit, restrict or hinder the construction, placing in service and operation of structural subsystem. In particular, checks may not be required which already have been carried out:

- as a part of the procedure for granting EC Declaration of verification of the subsystem laid down by this Law or
- subsystem which before or after entering into force of this Law is in advanced stage of realization, with a view to verifying compliance with identical requirements under identical operational conditions.

Conformity with the technical specifications of interoperability and national rules

Article 16

(1) A structural subsystem constituting the rail system and which is covered by the EC Declaration of verification shall be considered as being interoperable and meet the essential requirements concerning it. The verification of the interoperability, in accordance with the essential requirements, of the structural subsystem which constituting the rail system shall be established by technical specifications for that subsystem, if they exist.

(2) The Directorate prepares list of technical rules for each subsystem which are being used for implementation of the essential requirements, whether for the appropriate subsystem:

- no relevant technical specification exist or
- a derogation has been notified under Article 9 of this Law or
- a specific case requires the application of technical rules which are not included in the relevant technical specification.

(3) The list referred to in paragraph 2 of this Article is published:

- each time when the list of technical rules needs amendments or
- after the derogation has been notified or
- after the publishing of the relevant technical specification.

(4) In case when the structural subsystem is designed and constructed in accordance with paragraph 2, item 3 of this Law, in that case the procedure of verification is conducted by a designated body in accordance with the procedure referred to in Article 17 of this Law.

(5) The list of technical rules referred to in paragraph 2 of this Law is published on the website of the Directorate and is available for infrastructure manager, railway undertakings, and applicants for authorization for placing in service.

Procedure for establishing the EC Declaration of verification of a subsystem

Article 17

(1) For granting the EC Declaration of verification of a subsystem, the applicants submit an application to the Notified body for performance of the procedure of EC verification. The application for granting of the EC declaration of verification of a subsystem may be submitted by a contracting entity or a manufacturer or their authorized representative.

(2) The Notified body shall begin the procedure for the EC verification of a subsystem at design stage and cover the entire manufacture period until the phase of acceptance of the subsystem, before the subsystem is placed in service.

(3) The Notified body, in the procedure of the EC verification of a subsystem cover verification of the interfaces of the subsystem in question with the system into which is incorporated, based on the information available in the relevant technical specification and in the registers referred to in Article 30 and 31 of this Law.

(4) The Notified body, during the procedure of the EC verification of a subsystem, shall be responsible for compiling the technical file that has to accompanied the EC Declaration of verification of a subsystem. This technical file contains all the necessary documents for the characteristics of the subsystem, all the documents certifying conformity of the interoperability constituents, as well as elements related to the conditions and limits of use of a subsystem, as well as instructions concerning servicing, a constant or routine monitoring, adjustment and maintenance.

(5) The Notified body may issue intermediate statement of verification to cover certain stages of the verification procedure or certain parts of the subsystem, where the procedure for issuing EC Declaration of verification of a subsystem shall apply.

(6) The Notified body may issue a certificate of conformity for a series of subsystems or certain parts of those subsystems, if that is stated in the relevant technical specifications of those subsystems.

(7) The procedure for granting the EC Declaration of verification of a subsystem and the contents of the EC Declaration of verification of a subsystem is determined by the Minister of transport and communications.

Noncompliance of subsystems with essential requirements

Article 18

(1) Whether the inspection by Directorate finds that structural subsystem for which an EC declaration of verification is granted and accompanied by the technical file, does not fully comply with the provisions of this Law, and in particular does not meet the essential requirements, may be requested that additional checks have to be carried out.

(2) In a case of additional checks, it shall be stated whether fails to be in comply is a result of:

- a) noncompliance with the essential requirements or with technical specifications or incorrect application of the technical specifications. In that case, the notified body which issued the EC Declaration is being informed and shall be requested to take the appropriate measures.
- b) inadequacy of the stated technical specification, where a procedure for amending the technical specification is being initiated.

Placing in service of existing subsystems after renewal or upgrading

Article 19

(1) In case of renewal or upgrading of an existing subsystem, the contracting entity or the manufacturer submits a file with project description to the Directorate, after which the Directorate shall examine this file, taking account of the implementation strategy indicated in the relevant technical specification which has been applied during the granting of the EC Declaration of verification of a subsystem and shall decide whether extend of the work means that the new authorization for placing in service is needed in accordance with this Law.

(2) New authorization for placing in service shall be required when the overall safety level of the subsystem concerned may be affected by the works envisaged described in the file. If new authorization is needed, shall be decided to what extend the relevant technical specifications needed to be applied in the project. The decision shall be issued no later than four months after the submission of the complete file by the applicant.

(3) In case when a new authorization is required and if the relevant technical specification was not fully applied, the Directorate publishes the following information for:

- the reason why the technical specification is not fully applied,
- the technical characteristics applicable instead of the relevant technical specification and
- in case of the technical characteristics, the designated bodies responsible for applying the verification procedure referred to Article 17 of this Law.

VI. RAILWAY VEHICLES

Authorization for placing in service of vehicles

Article 20

- (1) Before being use on a network, a vehicle shall be authorized to be placed in service issued by the Directorate.
- (2) A vehicle in conformity with the technical specifications shall be authorized in accordance with Article 21 or 22 of this Law.
- (3) A vehicle that is not in conformity with the technical specification shall be authorized in accordance with Article 23 and 24 of this Law.
- (4) A vehicle which conforms to an authorized type shall be authorized in accordance with Article 25 of this Law.
- (5) On the territory of the Republic of Macedonia authorization for placing in service issued by NSA of other state from European Union is being recognized, only if they are not in conflict with the provisions referred to in Article 22 and 24 of this Law for additional authorizations. The Directorate, in accordance with the national rules or the provisions of this Law, decides whether additional authorizations are needed in accordance with Article 22 of this Law, when the vehicles are in conformity with the technical specifications or in accordance with Article 24 when the vehicles are not in conformity.
- (6) The application for issuing authorization for placing in service shall be subject of decision by the Directorate in accordance with Article 21 and 22 of this Law or Article 23 and 24 of this Law. The authorization to place in service may stipulate conditions of use and other restrictions.
- (7) The decisions brought by the Directorate for refusing the application for authorization to put in service of a vehicle shall be duly substantiated. The applicant, within one month period from receiving the negative decision, may request from the Directorate to review the decision based on justified reasons. In that case, the Directorate, within two months of receiving the receipt of the appeal shall confirm or reverse its decision. If the decision is confirmed, the applicant may submit appeal to the Administrative Court of the Republic of Macedonia within 30 days of the receipt of the decision.
- (8) In the absence of a decision brought by the Directorate as referred to in Article 22, paragraph 7 and Article 24, paragraph 6 of this Law, within the prescribed time limit, the placing in service of the vehicle in question shall be deemed to have been authorized after period of three months starting at the end of the time limits referred to in Article 22, paragraph 7 and Article 24, paragraph 6 of this Law. These authorizations are valid only for the network for which the Directorate did not react within the prescribed time limits.
- (9) If the Directorate intends to revoke an authorization to place in service a vehicle granted by itself or authorization granted to the applicant in accordance with paragraph 8 of this Law, in that case, the Directorate shall use the procedure for revision of the safety certificate in accordance with Article 19, paragraphs 10, 11, 12, 13 and 14 from the Law on railway system or, if possible, acts in accordance with the procedure for revision of the safety authorization in accordance with Article 22, paragraphs 3, 4 and 5 of the Law on railway system.
- (10) In case of appeal procedure, the Administrative Court of the Republic of Macedonia may request for a professional opinion of independent bodies, which, within one month shall submit the professional opinion to the applicant that is the Administrative Court of the Republic of Macedonia and the Directorate which refused to grant the authorization.
- (11) The vehicles for international usage which travel to countries in which the track gauge is different from that of the main railway network in the Republic of Macedonia, and for which derogation may be granted in accordance with Article 9, paragraph 5 and 6 of this Law or which are subject of a specific case, in accordance with the national rules referred to in Article 21 and 23 of this Law, international agreements shall be signed, if they are in accordance with this and other laws.

(12) The authorizations for placing in services granted before entering into force of this Law, including the authorisation issued in accordance with the international agreements, in particular RIC (Regolamento Internazionale Carrozze) and RIV (Regolamento Internazionale Veicoli), shall remain valid in accordance with the conditions under which authorization have being granted and the same have priority when Article 21 and 24 of this Law are being applied.

(13) The Directorate may grant an authorization to place in service a series of vehicles. In order to do so, the Directorate shall notify the applicant of the procedure which must be followed.

(14) The authorization for placing in service granted in accordance with this Article, shall be in comply with other conditions imposed on the railway undertakings and the infrastructure managers for operating such vehicles on the relevant network, in accordance with Article 9 and 10 of the Law on safety in the railway system and Article 19 and 22 of the Law on railway system.

First authorization for placing in service of TSI confirmed vehicles Article 21

(1) The provisions of this Article apply to the vehicles which are in conformity with the relevant technical specifications which are in force at the moment of placing in service, if a significant part of the essential requirements is laid down in the technical specifications and if the relevant technical specifications on vehicle has enter into force and is applicable.

(2) The first authorization for placing in service shall be granted by the Directorate:

- a) if all the structural subsystems of the vehicle have been authorized in conformity with the EC Declaration of verification of a subsystem in accordance with Article 14, 15, 16, 17, 18 and 19 of this Law, the authorization shall be granted without further checks;
- b) if the vehicles bear all necessary EC Declarations of verification, in accordance with Article 17 of this law, the criteria which the Directorate may check with the view to granting and authorization for placing in service may concern only:
 - technical compatibility between the vehicles' relevant subsystems and their safe integration in accordance with Article 14, paragraph 1 of this Law;
 - technical compatibility between the vehicle and the network concerned;
 - national rules which apply to the open points;
 - national rules which apply to the specific cases identified in the relevant technical specifications.

Additional authorizations for placing in service of TSI confirmed vehicles Article 22

(1) Vehicle which is in complete conformity with the technical specifications covering all aspects of the relevant subsystems without specific cases and open points related to the technical compatibility between the vehicle and the railway network shall not be subject to additional authorization for placing in service, as long as they run on TSI confirmed network or under the conditions specified in the relevant technical specifications.

(2) Vehicles placed in service in accordance with Article 21 of this Law, and which are not covered with paragraph 1 of this Article, shall be obligatory to obtain additional authorization in accordance with the provisions referred to in paragraph 3 to 7 of this Law.

(3) The applicant shall submit an application to the Directorate with a file on the vehicle or the type of vehicle and intended use on the network. The file contains:

- a) documentary evidence that placing in services of a vehicle has been authorized in accordance with Article 21 of this Law;

- b) a copy of the technical file of the vehicle, in the manner described in the EC Declaration of verification of a subsystem in accordance with Article 17 of this Law. This shall include, in the case of vehicles equipped with data recorders, information for the procedure for data-collection, which permits reading and evaluation, as long as this information is not harmonized by the corresponding technical specification;
- c) records showing the history of maintenance of the vehicle, and where applicable technical modifications undertaken after the authorization;
- d) evidence on technical and operational characteristics that shows that the vehicle is compatible with the infrastructure and fixed installations, including the climate conditions, the energy supply system, the control-command and signaling system, track gauge and infrastructure gauge, maximum permitted axle load and other constraints of the railway network.

(4) The criteria checked by the Directorate may concern only to:

- the technical compatibility between the vehicle and the appropriate network, including the national rules applicable to the open points needed for ensuring such compatibility.
- national rules applicable to specific cases, which are identified in the relevant technical specifications.

(5) The Directorate may request additional information to be supplied, risk analysis to be carried out in accordance with Article 6, item 1 of the Law on safety in the railway system or tests to be conducted on the network in order to verify the criteria referred to paragraph 4 of this Article. After the adoption of the referent document in accordance with Article 26 of this Law, the Directorate may only carry out such verification on the basis of the national rules related to Group B or C, stated in the document.

(6) The Directorate, after the consultations with the applicant, shall define the scope and the content of additional information, the risk analysis and the tests which were requested. The infrastructure manager in consultation with the applicant shall make an effort to ensure that the tests take place within three months of the applicants' request. Where appropriate, the Directorate shall take measures to ensure that the tests take place.

(7) The Directorate after the application for issuing authorization for placing in service submitted by the applicant, in accordance with the provision of this Law, shall take a decision as soon as possible and not later than:

- a) two months after the submission of the file referred to in paragraph 3 of this Article;
- b) one month after the provision of any additional information requested by the Directorate and
- c) one month after the provision of the results of the tests requested by the Directorate.

First authorization for placing in services of a non- TSI's confirmed vehicles

Article 23

(1) The provisions of this Article shall apply to vehicles which are not in conformity with all the relevant technical specifications which are in force at the moment of placing in service, including vehicles which are subject of derogations or where a significant part of the essential requirements is not laid down in one or more technical specifications.

(2) The first authorization for placing in services shall be granted by the Directorate as follows:

- for the technical aspects covered by a technical specification, if any, the EC verification procedure shall apply;
- for the other technical aspects, the national rules are determined in Article 16, paragraph 2, 3, 4 and 5 of this Law and Article 8 of the Law on safety in the railway system shall apply.

(3) The first authorization for placing in service shall be valid only on the network in the Republic of Macedonia.

Additional authorization for placing in services of non-TSI conformed vehicles
Article 24

- (1) In the case of vehicles authorized to be placed in services by one country member of the European Union, which are in accordance with Article 20 paragraph 12 or Article 23 of this Law, the Directorate may decide in accordance with this Article whether additional authorizations to place in service are necessary on the territory of the Republic of Macedonia.
- (2) The applicant shall submit a written application to the Directorate, together with the technical file on the vehicle or type of vehicle and its planned use of the network. The file contains:
 - a) documentary evidence that the placing in services of vehicle has been authorized another State together with the documentation of the procedure which was performed, in order to show that the vehicle complied with the safety requirements in force, including the information for derogation which were granted or enjoyed in accordance with Article 9 of this Law;
 - b) technical data, maintenance programme and operation characteristics. This includes, in case of vehicles equipped with data recorders, information of data collection procedure, permitting read out and evaluation as it is stated in Article 15, paragraph (3), item c of the Law on safety in the railway system;
 - c) records for the history of operation, maintenance, and if necessary, for the technical modification undertaken after the authorization;
 - d) evidence for the technical and operation characteristics that show that the vehicle is compatible with the infrastructure and the fixed installations, including the climate conditions, energy supply system, control command and signal system, track gauge and the infrastructure gauge, maximum permitted axle load and other constrains of the network.
- (3) information referred to in Paragraph 2, item a and b of this Article may not be call into question by the Directorate, unless the Directorate can prove, without confronting Article 15 of this Law, existence of substantial safety risk. After the adoption of the referent document referred to in Article 26 of this Law, the Directorate may not invoke in this regard any Group A rule stated in the document.
- (4) The Directorate may request for providing additional information, risk analysis to be carried out in accordance with Article 6, item 1 of the Law on safety in the railway system or tests to be conducted on the network in order to verify that information stated in paragraph 2, item c and d of this Article are in accordance with the national rules which are in force or with Article 16 of this Law. After the adoption of the referent document in accordance with Article 26 of this Law, the Directorate may perform only verification based on the national rules which apply to Group B or C, stated in the document.
- (5) After the consultations with the applicant, the Directorate determines the scope and the content of the additional information, risk analysis or tests which were requested. The infrastructure manager, in consultations with the applicant, shall make effort to ensure that the testing within 3 months since the request was submitted by the applicant. If necessary, the Directorate shall make measures to ensure that the tests take place.
- (6) After the submission of the application in accordance with this Article, the Directorate decides within shortest period of:
 - a) four months after the submission of the technical file in accordance with paragraph 2 of this Article;
 - b) two months after the provision of the additional information or risk analysis requested by the Directorate in accordance with paragraph 4 of this Article and
 - c) two months after the provision of the results of the tests requested by the Directorate in accordance with paragraph 4 of this Article.

(7) The form and the contents of the authorization for placing in service, as well as the additional authorization referred to in Article 21, 22, 23 and 24 is determined by the Minister of transport and communications.

Authorization of types of vehicles

Article 25

- (1) The Directorate may grant an authorization for types of vehicles.
- (2) If the Directorate authorized a vehicle, it has also, at the same time, authorized a type of vehicle.
- (3) Vehicle, which confirms to authorize type, based on declaration for conformity to this type submitted by the applicant without any further checks. If the relevant technical specifications and national rules on the bases on which a type of vehicle was authorized have been changed, the Directorate shall decide whether the already granted authorizations remain valid or should be renewed. The criteria checked by the Directorate in case of renewal of an authorization of the type, may only concern the changed rules. The renewal of the authorization for type of vehicle does not effect authorization of vehicle already granted on the bases of previously authorized type.
- (4) The form and the contents of the declaration for conformity to type are determined by the Minister for transport and communications.
- (5) The declaration of conformity of the type shall be grant for:
 - a) TSI conform vehicles, the verification procedure of the relevant;
 - b) non-TSI conform vehicles, the verification procedure as determined by module D and E, determined in the act of Article 17 of this Law. If necessary, the Directorate may adopt an ad hock procedure for verification.
- (6) The applicant may request a type authorization in several States at the same time. In that case, the NSAs shall cooperate in order to simplify the procedure and minimize the administrative efforts.
- (7) The type authorization shall be registered in the national registry of authorized types of vehicles referred to in Article 30 of this Law.

Classification of the national rules

Article 26

- (1) In order to facility the procedure for authorizing the placing in service of vehicles in accordance with Article 24 of this Law, the national rules are classified in three groups:
 - Group A which covers: international standards, national rules which are considered equal to the national rules in the other States, regarding the railway safety terms.
 - Group B which covers: all rules which are not in the scope of Group A or Group C, or that it has not yet been possible to be classified in one of these groups.
 - Group C which covers: rules that are strictly necessary and associate with technical infrastructure characteristics, in order to ensure safe and interoperable use in the network concern.
- (2) The Directorate, if necessary, cooperates with the European Railway Agency for the preparation of the referent document which contains the national rules which apply to the procedure for placing in service of a vehicle.

(3) The parameters which should be checked, in conjunction with placing in service of non-TSI vehicle are determined by the minister of transport and communications.

Notified bodies

Article 27

(1) The implementation of the procedure for granting an EC Declaration of conformity or suitability for use of the interoperability constituents referred to in Article 12 of this Law and the procedure for granting an EC Declaration for verification of the subsystem referred to in Article 17 of this Law is performed by notified bodies. Each Notification body has certain area of responsibility and ID number.

(2) The manufacturer or their authorized representatives for manufacturing the interoperability constituents and vehicles may in the procedure for assessment of conformity and verification of a subsystem may include notified bodies which are not seated in the Republic of Macedonia, and which is on the list of notified bodies published in the Official Journal of the European Union.

(3) The authorization for performing the assessment of conformity or suitability for use of the interoperability constituents and verification of a subsystem is issued by the Minister of Economy upon a written application submitted by the legal entity.

(4) The body for issuing the authorization for performance referred to in paragraph (1) of this Article, publishes the list of notified bodies, their ID number and the areas of responsibility in the Official Gazette of the Republic of Macedonia and the same is being updated.

(5) For granting the authorization for performing the assessment of conformity or suitability for use of the interoperability constituents and verification of a subsystem the notified body must fulfill the following criteria:

- to be seated in the territory of the Republic of Macedonia;
- to be registered for performance of the activity;
- not to be in the procedure of bankruptcy;
- to be insured in an insurance company and to submit a written proof that it is capable to recompense the possible damage in accordance with the national and international law which incurred in respect of responsibility in the activity;
- to have employed at least three persons with higher education in the area of the technical, legal and economic sciences, with working experience over five years in the area of the railway traffic and railway infrastructure, with active knowledge of one foreign language and knowledge of the rules in the area of the railway;
- capability for preparation of documents necessary for registration of the controls performed, administrative tasks related to the controls and should have access to the equipment necessary for the controls and
- the staff should own a proof for the appropriate performance of technical and vocational training.

(6) The notified bodies for performance of the procedure for assessment of conformity or suitability for use of the interoperability constituents and verification of a subsystem shall be notified by the Ministry of economy in the European Commission. In the notification, the Minister also states the area and the tasks of the notified bodies.

(7) The Director and the staff responsible for carrying out the checks must not be included directly or as authorized representatives in the design, manufacture, construction or marketing or maintenance of the interoperability constituents, or the subsystems or their use. This does not exclude the possibility for exchange of technical information between the manufacturer and the body.

(8) The Director and the staff responsible for carrying out the checks perform the same with the greatest professional integrity and technical capability and must be free from any pressure or incentives, especially of financial kind, which may influence their judgment or the results of their inspection, especially from people or groups affected by the results of the checks.

(9) The notified body and the staff responsible for the checks must be independent of the authority designated to issue authorization for placing in service in accordance with this Law, licenses for performance of public railway transport, safety certificates and safety authorizations in accordance with the Law on railway system, as well as from the bodies in charge of the investigations in the event of accidents.

(10) The independence of the staff responsible for inspections must be guaranteed. Not a single authorized person may be awarded based on the number of inspection conducted or based on the results of the inspections.

(11) The staff of the body is obliged with professional secrecy relating to what they find out in the performance of their obligations in accordance with this and other laws.

(12) The body which grants authorizations may withdraw the same if they assess that the notified body does not fulfill the conditions referred to in this Article.

VII. REGISTERS OF NETWORK AND VEHICLES

Vehicle Numbering System

Article 28

(1) All the vehicles placed in service on the railway system have a European vehicle number (further referred to as EVN) issued when the first authorization for placing in service is granted.

(2) The applicant, for the first authorization shall be responsible for the marking of the vehicle in question with the EVN issued.

(3) The manner of marking of EVN is specified in the technical specification on operation and traffic management.

(4) Each vehicle receives MNV just once, except it is otherwise specified in the technical specification for operation and traffic management.

(5) In case when a vehicle that operated or is intended for operation from or for another State where the track gauge is different from the one on the main railway network in the other State, their State may accept the vehicle if it is clearly identified according to different coding system.

National Vehicle Register

Article 29

(1) The Directorate shall keep register of vehicles authorized be place in service for a first time in the territory of the Republic of Macedonia. The Register must meet the following criteria:

- shall comply with the common specifications referred to in paragraph (2) of this Article;

- shall be updated by the Directorate;

- shall be acceptable to the authorized inspectors, the Committee for management of serious accidents, accidents and incidents on the railway system, the Agency for regulation of the railway sector, the railway undertaking and infrastructure manager, as well as to the people and organizations registering vehicles or identified in the Register.

(2) For each vehicle, the Register shall contain at least the following information:

- European vehicle number (EVN);
- number of EC Declaration of verification and the body which issued it;
- the number of the European Register of authorized types of vehicles in accordance with Article 30;
- data for the owner of the vehicle and the keeper;
- restriction of how the vehicle may be used;
- data for entity in charge of maintenance.

(3) The registration holder shall immediately declare any modification to the data registered in the National Vehicle Register, destruction of the vehicle or decision that they will no longer register the vehicle, to the Directorate.

(4) The National Vehicle Register shall be electronically linked with the Registries of the vehicle from European Railway Agency. The Directorate shall update its National Vehicle Register with the changes made in the register and inform the European Railway Agency for each change made.

(5) In cases of vehicles placed in service for the first time in the Republic of Macedonia, and they are authorized for placing in service on their territory, the railway undertaking or keeper shall ensure that the data referred to in paragraph (2), item 4, 5 and 6 of this Article can be retrieved through the National Vehicle Register or through European Railway Agency. The data referred to in paragraph (2), item 6 may be substituted by safety critical data related to the schedule of maintenance.

(6) The form, contents and manner of keeping the registry referred to in paragraph 1 of this Article are determined by the Ministry who manages the organ of the state management authorized for performance of the work in the area of the railway traffic and railway substructure.

Register of authorized types of vehicles

Article 30

(1) The Directorate shall set up and keep a register of authorized types of vehicles for placing in service on the railway network, which is available to the public and electronically acceptable and is linked with the European Railway Agency's Register.

(2) The Register referred to in paragraph (1) of this Article shall contain the following data for each type of vehicle:

- the technical characteristics of the type of vehicle, as it is defined in the relevant technical specifications;
- name of the manufacturer;
- authorization for types of vehicles, including all the restrictions or withdrawals.

(3) When an authorization of type is granted, modified, suspended and withdrawn, the Directorate shall inform the European Railway Agency in order for them to update their register.

(4) The form, contents and manner of keeping the register referred to in paragraph (1) of this Article are determined by the minister of transport and communications.

Register of the railway infrastructure

Article 31

(1) The Directorate shall set up and keep the Register of the railway infrastructure. The register shall indicate the main features of each subsystem or part of a subsystem and their correlation with the features determined in accordance with the technical specifications. Each technical specification shall indicate precisely what information must be included in the register of the railway infrastructure.

(2) The form, contents and manner of keeping the register referred to in paragraph (1) of this Article are determined by the minister of transport and communications.

VIII. SURVEILLANCE

Article 32

The surveillance on the implementation of the provisions of this law and the regulations referred to in it, is performed by the Ministry of transport and communications.

Article 33

(1) The inspection surveillance on the fulfillment of the requests referred to in this Law and the regulations adopted based on this Law regarding the sub-systems, including the components and railway vehicles is performed by the Direction for safety in the railway system.

(2) The inspectors for railway traffic and railway substructure, except for the obligations which arise from other regulations, based on this Law also perform inspection of the documents issued for the accordance, the technical documentation for railway sub-systems, the components and the railway vehicles and undertake measures for withdrawal of the documents for adequacy if the same are inadequate.

(3) If the Direction for safety assesses that there was a violation of the provisions referred to in this Law, it will bring a decision which will order a removal of the irregularities and will determine a deadline for their removal, it will prohibit the launching of inadequate railway sub-systems, components and railway vehicles.

(4) Against the decision of the Direction referred to in paragraph 3 of this Article, an appeal is allowed within 8 days since the day of the reception of the decision to the Minister who manages the organ of the state management empowered for performance of the work in the area of the railway traffic and the railway substructure.

(5) The appeal does not postpone the execution of the decision.

IX. SANCTIONS

Article 34

(1) A fine amounting from 3.000 EUR to 5.000 EUR in MKD, will be imposed to for infringement to a legal entity if:

- launches a sub-system without a certificate for launching (Article 19);
- launches a railway vehicle without a certificate for launching (Article 20);
- implements a procedure for assessment of adequacy without authorization (Article 26);
- does not label the vehicle with the MNV issued by the Direction (Article 28);
- does not report the changes in the data registered in the National registry of vehicles (Article 29, paragraph 3);
- does not act upon the decision of an inspector (Article 33, paragraph 3).

(2) A fine amounting from 1.500 EUR to 2.000 EUR in MKD, for the infringement referred to in paragraph 1 of this Article, will be imposed for infringement to the person responsible within the legal entity.

X. FINAL PROVISIONS

Article 35

The provisions foreseen by this Law will be adopted within six months after the entering into force of this Law.

Article 36

By the accession of Republic of Macedonia into the European Union shall apply international agreements RIC (Regolamento Internazionale Carrozze), RIV (Regolamento Internazionale Veicoli) or COTIFF (Intergovernmental Organization for International Caggiage by Rail) or technical specification for interoperability of subsystems.

Article 37

With entering into force of this Law, the validity of Article 12 referred to in the Law on safety of the railway system, shall expires.

Article 38

This Law enters into force on the eighth (8th) day since the publication in the Official Gazette of the Republic of Macedonia.