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DECLARATIONS IN THE SCOPE OF VEHICLE APPROVAL

Analysis of the differences between EU and COTIF provisions

1. INTRODUCTION

At WG TECH 31 in Rome, there was a discussion about the differences between EU law and COTIF concerning the voluntary or mandatory nature of declarations of ~~verification~~conformity for interoperability constituents (ICs).

In EU law, the independent assessment of and declarations for ICs are generally mandatory, whereas under COTIF, it is not mandatory to assess ICs separately. If not assessed separately, they must be assessed as part of the subsystem. In order to avoid ambiguities or discrepancies between EU and national law on the one hand and COTIF on the other, COTIF clarifies that assessment of ICs as part of the subsystem is only possible when permitted by the law applicable in the state concerned.

The question raised at WG TECH concerned declarations for ICs, but it is interesting to enlarge the scope of the question to include declarations not only for ICs, but also for subsystems.

This document highlights the essential differences between EU law and COTIF with regard to such declarations. It also provides a summary overview of the assessment modules and corresponding certificates and declarations for both ICs and subsystems. It then analyses these differences and their relevance, with a view to supporting a discussion on this subject. Lastly, the document includes some suggestions for further debate on the purpose of ICs and declarations in COTIF.

2. GENERAL DIFFERENCES BETWEEN EU RAILWAY LAW AND COTIF

2.1. EU RAILWAY LAW

This paper summarises the background of EU legislation concerning railway equipment. This is relevant because the provisions of APTU, ATMF and the UTPs are largely based on the EU provisions.

Since the early 1990s, the EU has implemented consecutive packages of legislation to harmonise and connect the railway markets of the EU Member States. The objectives include opening the market to provide international and national railway services and opening the railway equipment supply market.

With regard to the opening of the supply market, it was necessary to harmonise the requirements for railway equipment across the EU. To this end, EU railway legislation was aligned with generic EU product legislation referred to as the New Legislative Framework (and previously as the New Approach and Global Approach). This framework not only harmonises the product requirements, but also conformity assessment and market surveillance.

The general principles can be summarised as follows: a directive concerning a particular product group (e.g. medical equipment, machinery, toys, pressure vessels) sets out the so-called essential requirements for a product. No product may be marketed in the EU without meeting the essential requirements. Standards devised by standardisation bodies set out best practices to meet the essential requirements. These are referred to as harmonised standards. Complying with harmonised standards is not mandatory, but provides presumption of conformity with the essential requirements. When not following the harmonised standards the applicant must prove conformity with the essential requirements by other (robust) means. Assessment of conformity with the essential requirements typically involves a Notified Body, which performs third party (independent) assessments. In the end the applicant or manufacturer declares full responsibility for the product's conformity with all legal requirements and will be liable if it later turns out that there are issues with the product.

For the product groups concerned, this EU framework replaces national legislation. It therefore avoids manufacturers' having to receive permission based on national provisions in each state.

The EU Interoperability Directive distinguishes interoperability constituents (ICs), subsystems (such as rolling stock and infrastructure) and vehicles.

Conformity assessment of subsystems and (most) ICs must be performed by a Notified Body (third party assessor) at the request of an applicant or the manufacturer. The Notified Body will check whether the subsystem or IC complies with all the applicable TSI provisions. The applicant (in case of subsystems) or the manufacturer (in case of ICs) will bear full product responsibility and has to declare on his sole responsibility that all legal requirements have been complied with.

Vehicles are composed of subsystems and ICs. Vehicles require authorisation by an authorising entity (the EU Agency for Railways or the National Safety Authority). There is no vehicle-level third party assessment.

Vehicles which are in conformity with an authorised vehicle type will be authorised on the basis of a declaration of conformity to that type submitted by the applicant.

2.2. COTIF

Unlike EU law, COTIF has no objective in terms of opening the railway supply market. This means that meeting COTIF provisions will not give automatic access to the EU market (or any other market) and products approved according to EU law have no automatic right to be marketed in non-EU states which apply the relevant COTIF provisions.

Nevertheless, the COTIF provisions have largely been harmonised with EU railway law. On this basis, assessments and admissions (OTIF)/authorisations (EU) of railway vehicles (including their ICs) are mutually recognised in all EU and non-EU OTIF Member States that apply APTU and ATMF as far as using these vehicles in international traffic is concerned.

By analogy with EU law, COTIF also has dedicated provisions for vehicles, subsystems and ICs.

Whereas an important component in EU law is the declaration by an applicant, contracting entity or manufacturer that an IC or subsystem meets all the requirements, which means that it assumes full liability, such declarations are not mandatory in COTIF.

At present, COTIF provisions for subsystems only cover the subsystem rolling stock. There are currently no harmonised provisions for on-board CCS subsystems. Therefore, a vehicle admission for a vehicle including on-board CCS under OTIF is not equivalent in technical scope to an EU vehicle authorisation.

As in EU law, the principle of third party assessment of ICs and subsystems is required in COTIF. A significant difference between EU law and COTIF is that in COTIF the responsibilities for the different parties involved in the admission of vehicles can be adjusted, to a certain extent, for each state. Each state must notify the Secretary General of OTIF of its Competent Authority, which issues vehicle admissions. It is then up to the Competent Authority whether it performs conformity assessments itself or whether it transfers the competences to a public or private assessing entity. This means that in COTIF the third party assessor and the authorising entity can be the same body.

3. INTEROPERABILITY CONSTITUENTS

3.1. IN EU LAW

The framework allows manufacturers of ICs to certify and place their (IC) products on the EU market independently from rolling stock manufacturers. This allows ICs to be incorporated into different subsystems designed and manufactured by different entities. ICs are defined in the TSIs and if a product is not defined as an IC in the TSIs, it cannot be marketed as an IC, so the list of ICs in the TSIs is exhaustive.

Examples of ICs in the context of rail vehicles are wheels, pantograph, rear-end signals, automatic centre buffer couplers and inlet connections for water tanks. The complexity of designing and manufacturing the different ICs varies greatly (a water inlet connection is not as complex as an automatic coupler); in addition, their relevance to the safety of the rail system also differs.

The principle in EU law is that if a vehicle is fitted with a particular IC, the IC should have been assessed and certified as such before it was placed on the market, i.e. as an independent product. Not all types of vehicles will be fitted with all ICs (e.g. a diesel locomotive is unlikely to have a pantograph). Also, some ICs, such as the automatic centre buffer coupler, are not mandatory per se (other types of couplers may be used), but if a component of this nature is incorporated into a subsystem, then it must be an IC that conforms to the TSI.

The TSI parameters which concern the integration of the IC into the subsystem and the subsystem into the vehicle must, where relevant, subsequently be verified during conformity assessment of the subsystem or integration of the subsystem into the vehicle.

In order to take account of this variety and to avoid an undue burden for manufacturers, there are no fewer than ten different assessment modules (methods) for ICs. The TSIs define which modules are permitted for which IC.

Following application of (most of) the assessment modules for ICs, the manufacturer must issue a declaration of conformity and/or suitability for use. In so doing, the manufacturer declares, on his sole responsibility, that the IC meets all the TSI requirements applicable to it. For most modules the manufacturer is required to employ a Notified Body, which acts as a third party assessor. If so required by the assessment module, the Notified Body issues a certificate.

3.2. IN COTIF

As it is not the aim of COTIF to open the market, the need for ICs in COTIF is not obvious. Nevertheless, in order to maintain similarity of structure between the EU TSIs on the one hand and the UTPs on the other, the UTPs also define parameters for ICs. For COTIF the ICs may be assessed separately, but they may also be assessed as an integral part of the vehicle.

The situation in COTIF can be summarised as follows:

- APTU Article 8 § 4 d) requires UTPs to determine the ICs and their interfaces which are necessary to achieve interoperability. This is equivalent to how ICs must be covered in EU TSIs. This should be understood in the context that UTPs and TSIs need to be equivalent in order to allow the mutual acceptance of vehicles.
- ATMF Article 2 g) lays down a definition of ICs and Article 3 states that for the admission of ICs the requirements for the admission of vehicles apply *mutatis mutandis*. There are no further requirements in ATMF concerning ICs.
- Neither APTU nor ATMF stipulate whether ICs should be assessed for conformity with the UTPs independently or as part of the subsystem.
- The structural UTPs and UTP GEN-D establish the principle that the separate assessment of ICs is not mandatory in COTIF. However, separate assessment may be required by the law applicable in the state concerned.
- If not assessed separately, the components/parts of a subsystem corresponding to an IC must be assessed for compliance with all requirements as part of the subsystem. In such a case, no separate declaration for the IC will be issued. However, if an IC is assessed separately by application of the relevant modules, the declaration of conformity or declaration of suitability for use must be issued by the manufacturer.

Even if a declaration of conformity or declaration of suitability for use is issued by the manufacturer, it does not guarantee that this declaration is accepted by each state as a basis for marketing the product in the state concerned.

It is worth mentioning here that the Explanatory Report to COTIF (the part concerning ATMF) states the following:

With regard to Article 3 - Admission to international traffic: *The possibility of the technical admission of construction elements is useful because this allows simplification of subsequent technical admission, e.g., of a vehicle as a whole. However, in the case of the technical admission of a vehicle whose construction elements have already been approved, it is necessary to examine the way in which the elements operate together. It is self-evident that the approval of construction elements cannot replace the approval of a vehicle as a whole (Report on the 15th session, p. 40/41).*

With regard to Article 8 - Prescriptions applicable to railway infrastructure: *The procedure for admission of railway infrastructure to operation can remain subject to the national law. This, however, does not necessarily apply to the construction elements and equipment which are produced and technically approved in a Contracting State, but which are not used in that State, being used only in other Contracting States, e.g. rails, electric power supply installations. On this point, the APTU Uniform Rules and ATMF Uniform Rules are of importance for industrial and commercial policy.*

The following summary table lists the different declarations and certificates for ICs when assessed independently from the subsystem.

UTP GEN-D Modules for the procedures for assessment of interoperability constituents and corresponding certificates and declarations

<i>Module</i>	<i>Name</i>	<i>Assessing entity</i>	<i>Manufacturer</i>
CA	Internal production control	-	Declaration of conformity
CA1	Internal production control plus product verification by individual examination	Certificate of conformity	Declaration of conformity
CA2	Internal production control plus product verification at random intervals	Certificate of conformity	Declaration of conformity
CB	Type examinations	Type examination certificate	-
CC	Conformity to type based on internal production control	-	Declaration of conformity
CD	Conformity to type based on quality management system of the production process	<u>Quality management system approval-</u>	Declaration of conformity
CF	Conformity to type based on product verification	<u>-Certificate of conformity</u>	Declaration of conformity

CH	Conformity based on full quality management system	<u>Quality management system approval-</u>	Declaration of conformity
CH1	Conformity based on full quality management system plus design examination	<u>Quality management system approval</u> Design examination certificate	Declaration of conformity
CV	Type validation by in-service experience (suitability for use)	Certificate of suitability for use	Declaration of suitability for use

4. CONFORMITY ASSESSEMENT OF SUBSYSTEMS

There are several subsystems, as defined by UTP GEN-B. This section deals only with conformity assessment of the subsystem rolling stock, as this is the most relevant subsystem in the scope of ATMF. Nevertheless, other subsystems, such as infrastructure and energy, are also relevant to international traffic. The admission, including conformity assessment, of the latter is however subject to the provisions in force in the Contracting State in which the infrastructure is located (cf. ATMF Article 8 § 2).

Vehicles may consist of a combination of two subsystems: rolling stock and the on-board control-command and signalling (CCS). As the latter is not (yet) specified in UTPs, approval and admission in accordance with COTIF is for the time being limited to the rolling stock subsystem. If a vehicle also has an on-board CCS, in the absence of COTIF provisions its approval is subject to the provisions in force in the state concerned.

For these reasons this analysis deals only with the conformity assessment of the rolling stock subsystem.

4.1. EU LAW

The general principles of the EU legal framework are discussed in point 2.1.

Before a vehicle can be authorised, its subsystem(s) must be subject to so called “EC” verification. In this process the subsystem(s) are assessed for conformity to demonstrate they comply with all applicable legal provisions.

For the assessment of conformity the applicant issuing the EC declaration of verification for a mobile subsystem chooses a Notified Body recognised or accredited for this purpose. At the end of the verification procedure the Notified Body will issue a certificate of verification certifying that the subsystem complies with all applicable TSIs.

Where relevant, a so called Designated Body will also check and certify that the subsystem complies with the national rules notified for this purpose.

Based on the certificate(s) of verification, the applicant will declare, on his sole responsibility, that the subsystem(s) comply with all the legal requirements. Based on this EC declaration of verification the subsystems may be placed in service or on the EU market¹ (note: they may not yet be operated).

¹ Placing on the market of mobile subsystems is a concept introduced by the EU's 4th railway package, in Directive (EU) 2016/797. Until this Directive is transposed by all EU Member States the subsystems concerned may be subject of placing in service in accordance with Directive 2008/57/EC.

Before rolling stock, where relevant in combination with and integrated on-board part of CCS, may be operated as a vehicle, the vehicle must first be authorised. Vehicles are authorised at the request of an applicant by the authorising body, which is either the National Safety Authority or in the future also the EU Agency for Railways.

For this purpose the applicant for vehicle authorisation must provide the authorising body, in addition to the “EC” declaration of verification of each subsystem, evidence of:

- Technical compatibility between the vehicle and the network(s) on which the vehicle is intended to be used (defining the area of use), and
- Where relevant (meaning if the vehicle is composed of the subsystems RST and CCS), the technical compatibility and safe integration of the subsystems within the vehicle.

4.2. COTIF

As explained above, the technical provisions and the assessment procedures of subsystems are equivalent in COTIF and EU law. This ensures that if a subsystem complies with the technical provisions in EU law (TSIs), it will also comply with the technical provisions in COTIF (UTPs) and *vice versa*.

The responsibilities linked to the vehicle admission/authorisation and the liabilities are not the same under COTIF and EU law. Under COTIF, a vehicle’s certificate of operation is issued by the competent authority of a Contracting State and constitutes proof of the vehicle’s admission to international traffic.

It could be said that by applying COTIF, non-EU Member States’ authorities may claim a bigger role and take more responsibility for conformity assessment and vehicle admission than EU Member States can under EU law.

Approval of vehicles under COTIF:

- The objective of conformity assessment is to establish whether a subsystem complies with all UTP requirements applicable to it so that a competent authority can use the results of conformity assessment when issuing vehicle admission in accordance with ATMF.
- The applicant applies for assessment by an assessing entity (or the competent authority if this is also the assessing entity).
- Assessing entities must issue a certificate of verification and document the assessments carried out in an assessment report.
- The issuing of a declaration of verification by the applicant is not mandatory in COTIF.

UTP GEN-D Modules for the procedures for assessment of subsystems and corresponding certificates and declarations

<i>Module</i>	<i>Name</i>	<i>Assessing entity</i>	<i>Applicant</i>
SB	Type examination	UTP type examination certificate	-
SD	Quality management system of the production process	Quality management system approval UTP certificate of verification	(Optional) UTP declaration of verification
SF	Verification based on product verification	UTP certificate of verification	(Optional) UTP declaration of verification
SH1	Verification based on full quality management system plus design examination	Quality management system approval UTP design examination certificate UTP certificate of verification	(Optional) UTP declaration of verification

5. DISCUSSION

In order to further its aims concerning the common market and alignment of the rail supply market with other sectors, the EU has adopted a legal framework for verification of ICs and subsystems and the authorisation of vehicle types and individual vehicles before placing any of them on the EU market. For the sake of compatibility between the EU and COTIF provisions, this EU framework has partly been taken over in COTIF. It is debatable whether all these provisions serve a purpose in COTIF or they add unnecessary complexity. In particular, it might be worthwhile to discuss whether the concepts of ICs and declarations and their mutual recognition are necessary and useful.

5.1. ICs

APTU and ATMF do not stipulate any requirements concerning ICs. The only requirements concerning ICs are set out in UTPs, by transposing the EU TSI provisions on ICs. Where, in EU law, ICs must be assessed for conformity separately from the subsystem, the UTPs also permit ICs to be assessed as part of the subsystem (vehicle).

On the one hand, the voluntary nature of separate IC assessment suggests that the main reason for including ICs in COTIF was to align with EU law. On the other hand, specifying ICs in UTPs avoids having to re-check the parameters of ICs which have already been placed on the EU market, thus potentially simplifying COTIF admissions of vehicles which have EU-produced ICs in them.

Unlike vehicles, which can be used internationally on the basis of COTIF, ICs cannot be sold internationally solely on the basis of COTIF, as COTIF is not a trade agreement. At the same time, there is nothing to prevent states from also using COTIF provisions in the scope of their industrial and commercial policies. If a non-EU manufacturer of ICs would like to sell its IC products on the EU market, it could not assert rights under COTIF and would in principle have to apply EU legislation, including IC conformity assessment. Similarly, EU-produced ICs cannot be marketed outside the EU only on the basis of rights asserted under COTIF.

It may be useful to reflect on this and discuss whether ICs should remain a concept in future revisions of the UTPs. In such discussions it may be worth considering whether COTIF should include provisions for the mutual recognition of component certification, in particular to facilitate component replacement in the scope of repair and maintenance (spare parts). The rationale behind this is that the replacement of components of vehicles in international use (e.g. change of wheelset) is likely to need to be carried out not just in the state where the vehicle is registered. This may include more than what is specified today as ICs.

5.2. DECLARATIONS

Whereas in EU law, declarations by manufacturers and applicants concerning the legal compliance of their ICs and subsystems form an integral part of the EU product marketing framework, under COTIF these declarations are optional and do not serve the same purposes as in the EU.

It could be argued that referring to the declarations in COTIF is convenient for EU companies so that they can market their products outside the EU on the basis of COTIF. However, declarations for this purpose would not have to be accepted by non-EU states.

In the technical provisions of COTIF, UTP GEN-D in particular refers to declarations and their optional nature. If UTP GEN-D were to be revised in the future, it might be useful to discuss whether the reference to these declarations should be maintained.
