

## **Procedures for controlling the conformity of production of a vehicle, system, component, separate technical unit, part and equipment**

### **Background and legal basis of the Regulation**

The new Vehicles Act (82/2021) entered into force on 1 March 2021. Section 66 of the Act lays down provisions on procedures for monitoring the conformity of production. According to subsection 1 of the section, the manufacturer or representative of the manufacturer of a vehicle, system, component, separate technical unit, part and equipment is obliged to ensure that the product in question meets the requirements of the approved type or CE mark in terms of its structure, equipment and condition. Subsection 2 of the section lays down provisions on the obligation of the manufacturer or representative of the manufacturer to report any non-compliance. According to subsection 3 of the section, the approval authority must ensure that a sufficient procedure is in place to guarantee efficient monitoring of conformity before granting type-approval. Subsection 4 lays down provisions on initial assessments. In accordance with the legal provision, subsection 5 of the section lays down provisions on applicable procedures for different type-approvals. Subsection 6 lays down provisions on the procedures to be adhered to in EU type-approval in terms of written control plans and the product's conformity arrangements. Subsection 7 lays down provisions on the procedures to be adhered to in national type-approval and national small series type-approval.

This Regulation repeals the Finnish Transport and Communications Agency regulation on procedures for monitoring the conformity of production of a vehicle, system, component, separate technical unit, part and equipment (TRAFICOM/46660/03.04.03.00/2020).

By this Regulation, the Finnish Transport and Communications Agency issues under section 66, subsection 8 of the Vehicles Act regulations on the written control plans related to the control of conformity of production as regards national, UNECE, EC and EU type-approval as well as national small series type-approval and on product conformity arrangements deemed sufficient. The authority to issue regulations is based on section 66, subsection 8 of the Vehicles Act (82/2021). According to the legal provision, the Finnish Transport and Communications Agency may lay down more specific regulations on the written control plans related to the control of conformity of production as regards national, UNECE, EC and EU type-approval and national small series type-approval and sufficient conformity arrangements for the product.

### **Other related statutes and regulations**

The scope of application of this Regulation will be amended to also observe the monitoring of production conformity of studs and studded tyres. In terms of studs and tyre-stud combinations, a regulation on technical requirements for and type-approval of studded tyres for vehicles (TRAFICOM/383441/03.04.03.00/2022, hereinafter also the 'Regulation on studded tyres') would specify certain exceptions and additional requirements to be primarily adhered to.

## **Objective of the Regulation**

The legislative proposal on amending the Vehicles Act (HE 291/2022) is intended to enter into force in early 2023 (VN/6348/2020). The proposal includes the suggestion to amend section 66, subsection 8 to also cover EC type-approved vehicles in its authority to issue regulations. The objective of the present regulatory project is to carry out some of the changes required by the legislative amendment in the regulation issued by the Finnish Transport and Communications Agency. The changes are dependent on the progress of the legislative proposal.

Another objective of the regulatory project is to update regulations issued by the Finnish Transport and Communications Agency to have general production conformity control regulations to be included in this Regulation in the future. The objective is to transfer to this Regulation the general regulations on production conformity included in the Finnish Transport and Communications Agency Regulation on studded tyres. Indeed, in addition to ensuring that regulation as a whole is up to date, the objective of the Regulation is to clarify the legal state and harmonise the general requirements concerning production conformity control for various type-approved products and their manufacturers.

## **Other implementation options**

Legislative amendments require certain additions concerning the extensions of EC type-approvals to be made in the Regulation. According to Article 89(1) of the Framework Regulation on vehicles and their trailers, the regulation shall not invalidate any whole-vehicle type-approval or EU type-approval granted to vehicles or to systems, components or separate technical units by 31 August 2020. According to paragraph 2 of the Article, approval authorities shall grant extensions and revisions of whole-vehicle type-approvals and EU type-approvals to the vehicles, systems, components or separate technical units referred to in paragraph 1 of the Article in accordance with Articles 33 and 34. As concerns production conformity control, it is interpreted that, as a rule, EC type-approval extensions also refer to EU type-approvals in the context of the Framework Regulation.

General provisions concerning production conformity control would be transferred from the regulation on technical requirements for and type-approval of studded tyres to this Regulation in clearer terms. An alternative to extending the scope of application would be to impose corresponding requirements for the products in question in the manner described above based on section 66 of the Vehicles Act in the role of approval authority. The Regulation can, however, produce clearer, more transparent regulation that supports equality.

## **Preparatory work of the Regulation**

The draft of the Regulation was prepared by the Finnish Transport and Communications Agency. The Agency has presented the Regulation to stakeholders during the regulatory project.

The start of the project was announced on the Finnish Transport and Communications Agency website and communicated via email to those who subscribe to mailing list for the road transport regulation drafting process.

Written comments on the draft Regulation were requested between 2.6.2023 and 2.8.2023.

The request for comments was published on the Finnish Transport and Communications Agency website. The request was also sent via email to those who subscribe to the mailing list for the road transport regulation drafting process. The

finalised Regulation will be published on the Finnish Transport and Communications Agency website and in the Finlex online database. The issuing of the Regulation will be announced on the Finnish Transport and Communications Agency website and separately to stakeholders.

The draft Regulation was notified in accordance with the procedure for the provision of information in the field of technical regulations (Directive (EU) 2015/1535 of the European Parliament and the Council of the European Union).

## **Comments received through consultation**

The compilation of comments received through consultation is attached to the Explanatory notes.

## **Changes and assessment of the impact of the Regulation**

The Regulation has no significant financial impact nor does it affect accessibility. The Regulation supplements the legal provisions issued in acts and supports the practical application of the relevant acts.

As a rule, the Regulation will not impact the current status and the prerequisites for operation remain the same. The regulatory amendment will not affect approvals that are valid at the time of the entry into force of this Regulation, unless obligations based on other compelling regulation are applied to them, based on which the approval must be extended or the approval is not valid as is for any other reason. The Regulation aims to clarify the operating environment by transferring to this Regulation general requirements concerning production conformity control from the Regulation on technical requirements for and type-approval of studded tyres for vehicles. As regards content, the Regulation corresponds to the established operating model and offers clearer and stronger grounds to support business operations going forward. In part, the Regulation supports non-discrimination and equality by issuing shared, compelling rules.

## **Detailed rationale**

### **1 Scope of application**

By this Regulation, the Finnish Transport and Communications Agency will issue further regulations on the written control plans related to the control of conformity of production as regards national, UNECE, EC and EU type-approval as well as national small series type-approval and on sufficient product conformity arrangements. The Regulation is applied to the assessment of production conformity control of the type-approval applicant and holder. Conformity of production (CoP) refers to the correspondence of the products produced by the manufacturer with the original approved type.

In the future, the scope of application will be extended to cover the control of the conformity of production of all vehicles, systems, components, separate technical units, parts and equipment within the scope of application of the Vehicles Act (82/2021). In the government proposal for amending the Vehicles Act and related acts (HE 291/2022), section 66, subsection 8 of the Vehicles Act is proposed to be amended to also include EC type-approved vehicles in the scope of the Finnish Transport and Communications Agency's authority to issue regulations. In accordance with the government proposal, EC type-approval would be included in the scope of application. The conformity control procedures of studs and tyre-stud combinations covered by national type-approval will also be added to the scope of application. The Regulation on technical requirements for and type-approval of studded tyres for vehicles will, however, continue to provide more detailed

regulations concerning tyre–stud combinations, which correspond to the current legal state and shall be adhered to in addition to this Regulation. If the provisions of the two regulations deviate from each other, the Regulation on studded tyres shall take precedence.

According to section 66, subsection 4 of the Vehicles Act, the assessment of the scope of the initial assessments, arrangements concerning product conformity as well as the written control plans of the products can, for special reasons, be carried out less frequently than every 12 months, but at least every 24 months. The 12-month interval takes precedence, but for special reasons, the assessment could be carried out more flexibly once every 12–24 months. The special reason referred to in the Regulation could, for example, be that a more frequent assessment interval is deemed unnecessary based on risk assessment methods.

For the purposes of the Regulation, a control plan refers to a documented description of the methods and inspections that can be carried out to ensure that the product meets the requirements for type-approval throughout the validity of the type-approval.

## **2 Definitions**

Definitions will be transferred from subsection 1.1 to form a new section, section 2. In addition to this, the defined term “control plan” will be specified to refer to a written control plan in more specific terms than before.

## **3 Product conformity arrangements and their assessment**

Section 2 of the Regulation will be moved to create a new section, section 3, in addition to which the subsections of the section will undergo technical amendments. Going forward, provisions will be itemised in more detail by numbers. A reference to EC type-approval would be added to the title of the section.

The Regulation issues further provisions on the production conformity control procedures required by the authorities, which are used as basis for the authority to ensure that the production conformity control is sufficient. According to section 2, subsection 1, paragraph 48 of the Vehicles Act (82/2021), the manufacturer’s representative refers to the party that the manufacturer of the vehicle, system, component, separate technical unit, part or equipment has authorised to represent them in dealing with approval authorities and market surveillance authorities as well as act on its behalf in matters concerning type or individual approval.

The language of subsection 3.1 would be reviewed. The content of the subsection will not be amended. According to the section, the manufacturer must have a documented quality management system, which must cover the manufacture of the type-approved product. A quality management system in accordance with ISO 9001:2015 or a similar standard is considered such a documented quality management system. The provisions of subsection 3.1 will be applied to the manufacturer’s representative to the extent that the manufacturer’s representative, as the holder of the type-approval, participates in the manufacture of the product and in ensuring compliance with the requirements related to conformity with type-approval in the scope of the national type-approval to be granted.

According to subsection 3.2, the product manufacturing process must be steered and managed using a quality management system. The content of the subsection will not be amended.

Subsection 3.2.1 would provide the minimum requirements concerning the quality management system.

Point h of paragraph 6 would be amended to better correspond to the documents required by the paragraph in question. The requirement in question concerns previous production conformity assessment reports.

Paragraph 7 would be changed to include all possible approved products in addition to vehicles by adding the possible products of the scope of the entire CoP regulation. There is no reason to limit the requirement to vehicles only.

The new paragraph 8 in subsection 3.2.1 would cover the procedure of handling certificates of conformity (CoC) and the information in the certificates. The objective is to have manufacturers specify in more detail where the information on the certificate comes from, in addition to how they handle the certificate of conformity. Currently, the requirement concerns the EU and EC type-approval of vehicles as well as national small series type-approval. As far as certificates of conformity are concerned, it must be noted that the provisions concerning external documents specified in point c of paragraph 6, for example, also pertain to them.

The wording of paragraph 11 would be amended.

The provision concerning the additional requirements on quality management systems, concerning the tasks, responsibilities and authorisations of the people involved in the manufacturing process of the type-approved product, would be moved and made into a new paragraph, paragraph 13, based on relevancy. The purpose of this is to clarify the fact that the provision is as compelling as any other matter mentioned in the list. At the same time, the specific requirement of defining human resources related to the manufacture of a type-approved product would be removed, because the provision is in fact included in the definition of the tasks, responsibilities and authorisations of the people involved in the manufacturing process referred to in paragraph 13.

The language of the reference in subsection 3.2.2 would be reviewed. According to the subsection, the quality management system must contain written control plans. The provision refers to the written control plans of products to be type-approved referred to later in section 4.

According to subsection 3.2.3, the quality management system must be used to ensure that any components found to be non-conforming are not used in the manufacture of type-approved products or products that are found to be non-conforming are not made available on the market. The content of the subsection will not be amended.

According to subsection 3.2.4, the quality management system must also define and document the ways in which the conformity of products placed on the market is ensured. This procedure is also applied to vehicle prior notifications. The procedure must contain a comparison of the requirements and information determined in the type-approval with the approval documentation. If the procedure is based on sampling, this must also be defined. The content of the subsection will not be amended.

Additionally, according to subsection 3.2.5, the quality management system must contain an auditing programme, according to which internal audits are performed. The content of the subsection will not be amended.



If any changes are made to the quality management system, the changes must be implemented in a systematic manner in accordance with subsection 3.2.6 in order to ensure the continued conformity of the products covered by the type-approval. Systematic refers to an advance plan, and no changes shall be made without a proven plan for changes.

The last paragraph of subsection 2.1 of the regulation currently in force would be re-numbered as 3.2.7. In addition to provisions included in statutes, any future legal rules issued in the form of a regulation would be observed in this provision.

#### **4 Written control plan**

Section 3 of the Regulation will be re-numbered as section 4, in addition to which the subsections of the section will undergo technical amendments. In the future, the provisions will be itemised by numbers in more detail. Each type-approved product must have a written control plan, which the manufacturer uses to control the conformity of the product during the manufacture and placement on the market of the product. With this document, the manufacturer or manufacturer's representative can prove the sufficient procedures for ensuring conformity in the production of a type-approved product as part of their quality management system. A reference to EC type-approval will be added to the section.

According to subsection 4.1, the written control plan must contain a description of the object to be inspected, among other things. The description must contain the compelling legislation concerning the product and any tests applicable to the product due to the legislation. The structural parts of the product must also be itemised in the description, if necessary. The inspection method of the product, in turn, refers to the manner in which the inspection is carried out, such as the visual, written or physical inspection method. The frequency of inspecting the object refers to both the requirements based on legislation and the actual frequency. The information on the inspection and the person responsible for the procedure can be notified using the titles of the persons in charge of the inspections in the organisation, for example.

A new subsection, subsection 4.2, will be added to the Regulation, which will provide more detailed requirements for the content of the records of the written control plan. At the same time, the mention of information on the outcome of the inspection along with justifications in section 3, subsection 2, paragraph 5 of the regulation currently in force will be removed, because the mention is connected to the records mentioned in the new subsection 4.2. As far as content, the provision will in the future be included in what is provided in subsection 4.2.2. The new subsection 4.2.2 covers situations in which the written control plan also serves as the record.

Annex 1 to the Regulation would be removed to avoid any confusion. In the future, the Finnish Transport and Communications Agency will publish examples of how to draft the written control plan in the form of separate support materials. Examples will be removed from the Regulation to avoid any ambiguity in interpretation. In practice, the preconditions contain case-by-case discretion, meaning that a general example of the outline of the control plan cannot be directly applied in a manner that it could be referred to in the same way as a legal provision. The manufacturer must draft a written control plan based on the product and production in question.

Section 4 on entry into force and transitional provisions will be moved to create a new section, section 5. Any transitional provisions whose transitional period has elapsed at the time of the entry into force of the Regulation will be removed from the Regulation.

## **Entry into force**

The Regulation is intended to enter into force in early of the year 2024.

## **Appendices**

Compilation of comments