

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

Regulation background and legal basis

The new Vehicles Act (82/2021) entered into force on 1 March 2021. Section 66 of the Act provides for the control of conformity of production. According to subsection 1 of said section, where a vehicle, system, component, separate technical unit, part or equipment is supplied, the manufacturer and the manufacturer's representative are obliged to ensure that it conforms to the approved type or to the conditions of the CE marking in its structure, equipment and condition. Subsection 2 of the same section lays down the obligation of the manufacturer and the manufacturer's representative to report non-compliance. According to subsection 3 of the same section, prior to granting approval, the approval authority must ensure that there are sufficient procedures in place for ensuring that the control of conformity of production is efficient. Subsection 4 provides for the initial assessment. Subsection 5 lays down the applicable procedures for different type approvals. Subsection 6 lays down the procedures to be followed in EU type-approval with regard to written control plans and product conformity arrangements. Subsection 7 lays down the procedures to be followed in national type-approval and national small series type-approval.

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

Under this Regulation, the Finnish Transport and Communications Agency issues regulations on written control plans for the control of conformity of the production of national, E, EC and EU type-approval and national small series type-approval and on the product conformity arrangements deemed sufficient. The authority to issue regulations is laid down in section 66(8) of the Vehicles Act (82/2021). The Finnish Transport and Communications Agency may issue further regulations on the written control plans for the control of conformity of the production of national, E, EC and EU type-approval and national small series type-approval and on the product conformity arrangements deemed sufficient.

Other relevant provisions and regulations

The scope of this Regulation is also amended to take into account the control of conformity of the production of studs and studded tyres. In the case of studs and different tyre-stud combinations, the Regulation on the technical requirements and type-approval of studded tyres on a vehicle (TRAFICOM/383441/03.04.03.00/2022, henceforth also the 'Studded Tyre Regulation') would provide for certain derogations and additional conditions to be complied with as a matter of priority.

Objective of the Regulation

The Government Proposal for an Act amending the Vehicles Act (HE 291/2022) is planned to enter into force at the beginning of 2023 (VN/6348/2020). In the proposal project, it is proposed that section 66(8) be amended to include EC type-approved vehicles within the scope of the authority to issue regulations. The objective of this regulation project is to amend the Regulation of the Finnish Transport and Communications Agency to reflect the amendments made to legislation. The amendments depend on the progress of the legislative drafting.

In addition, the objective of the regulation project is to update the Regulations of the Finnish Transport and Communications Agency in such a way that in the future, general provisions on the control of conformity of production would be found in this Regulation. The intention is to transfer the general provisions concerning the control of conformity of production from the Finnish Transport and Communications Agency's Studded Tyre Regulation to this Regulation. The purpose of the Regulation is therefore not only to ensure that regulation is up-to-date, but also to clarify the legal situation and to equalise the general requirements for the control of conformity of production for the various types of products to be type-approved and for their manufacturers.

Other implementation options

The Regulation should be supplemented regarding to the extensions of EC type-approval as a result of legislative amendments made. According to Article 89(1) of the Framework Regulation for cars and their trailers, the Regulation does not invalidate a whole-vehicle type-approval or an EU type-approval of vehicles or systems, components or separate technical units granted by 31 August 2020. According to paragraph 2 of the same Article, approval authorities 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 same Article in accordance with Articles 33 and 34. As regards the control of conformity of production, the interpretation is that, in principle, an extension of EC type-approval is also an EU type-approval in the context of the Framework Regulation.

The general provisions on the control of conformity of production would be transferred more unambiguously from the Regulation on the technical requirements and type-approval of studded tyres under the scope of this Regulation. An alternative to the extension of the scope would be that the Finnish Transport and Communications Agency lays down, in its capacity as an approval authority, equivalent requirements for the products concerned as described above, pursuant to section 66 of the Vehicles Act. However, issuing a regulation can be used to produce clearer, more transparent regulation that fosters equality.

Drafting of the Regulation

The draft Regulation was produced by the Finnish Transport and Communications Agency. The Finnish Transport and Communications Agency presented the Regulation to stakeholders during the regulation project.

The commencement of the regulation project was notified on the website of the Finnish Transport and Communications Agency as well as via email to those that have subscribed to the mailing list for new road transport regulation being drafted.

Written statements on the draft Regulation have been requested to be submitted by xx.

The request for statements was published on the Finnish Transport and Communications Agency's website. In addition, the request for statements was sent by email to those that have subscribed to the mailing list for new road transport regulation being drafted. The finalised Regulation will be published on the Finnish Transport and Communications Agency's website and on Finlex. Information on the Regulation is posted on the Finnish Transport and Communications Agency's website and will be sent separately to stakeholders.

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

Content of statements submitted

Amendments and an assessment of the impact of the Regulation

The Regulation has no significant financial impacts, and it has no impact on accessibility. The Regulation supplements the legal provisions in force and supports application of the Act on a practical level.

Generally, the Regulation has no effect on the current state of affairs, and the prerequisites for operations will remain at their current level. Approvals in force at the time this Regulation enters into force are not affected by the amendments, unless they are subject to, for example, obligations arising from other binding regulation on the basis of which the approval must be extended or the approval as it currently stands is no longer valid for some other reason. The Regulation aims to clarify the operating environment by transferring the general requirements for the control of conformity of production from the Regulation on the technical requirements and type-approval of studded tyres on a vehicle to this Regulation. The content of the Regulation is consistent with the established operating model and will provide clearer and stronger grounds for supporting business operations in the future. The Regulation supports non-discrimination and equality by means of common binding rules.

Detailed rationale

1 Scope

With the Regulation, the Finnish Transport and Communications Agency issues more detailed regulations on the written control plans for the control of the conformity of the production of national, E, EC and EU type-approval and national small series type-approval and on the product conformity arrangements deemed sufficient. The Regulation applies to the assessment of the control of conformity of production by the applicants for type-approval and by the holders of type-approval. 'Conformity of production' (or 'CoP') refers to the conformity of the manufacturer's products with the original approved type.

The scope of application is extended to apply generally to the control of the conformity of production of all vehicles, systems, components, separate technical units, parts and equipment falling within the scope of the Vehicles Act (82/2021). The Government Proposal for an Act amending the Vehicles Act and related Acts (HE 291/2022) proposes that section 66(8) of the Vehicles Act is amended to include EC type-approved vehicles within the scope of the authority to issue regulations vested in the Finnish Transport and Communications Agency. Under the draft Act, EC type-approval would be added to the scope of the Act. Conformity control procedures for studs and tyre-stud combinations subject to national type-approval are also added to the scope as appropriate. However, further provisions on studs and tyre-stud combinations will be issued with the Regulation on the technical requirements and type-approval of studded tyres on a vehicle in the future and in line with current legislation, and these must be complied with in addition to this Regulation. In the event of any contradiction between provisions, the Studded Tyre Regulation shall prevail.

Under section 66(4) of the Vehicles Act, for special reasons, the assessment of the effectiveness of initial assessments and product conformity arrangements and the coverage of written product control plans may be carried out at intervals longer than every 12 months, although at least every 24 months. The 12-month interval is preferred, but for a special reason the assessment could be carried out more flexibly every 12 to 24 months. The specific reason referred to in the provision could be that a more frequent assessment interval is considered unnecessary on the basis of risk assessment methods, for example.

'Control plan' refers to a documented description of the procedures 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

The definitions are moved from section 1.1 to create a new chapter 2. In addition, the definition for the term 'control plan' is modified to refer more specifically to the written control plan.

3 Product conformity arrangements and their assessment

Chapter 2 becomes a new chapter 3, and technical amendments are made to the sections of the chapter. In the future, the provisions will be referred to by their number, which will be clearer. A reference to EC type-approval would be added to the title of the chapter.

The Regulation provides further provisions regulations on the procedures for the control of conformity of production as required by the authorities, based on which the authorities may ensure the sufficient control of conformity of production. According to section 2(1)(48) of the Vehicles Act (82/2021), 'manufacturer's representative' refers to a party authorised to represent the manufacturer of a vehicle, system, component, separate technical unit, part or equipment in their dealings with approval authorities and market surveillance authorities, and to act on their behalf in matters related to type or individual approvals.

Linguistic amendments would be made to section 3.1 of the Regulation. No substantive changes would be made to this section. According to the section, the manufacturer must have a documented quality management system in place that covers the manufacture of the type-approved product. A quality management system under ISO 9001:2015 or an equivalent standard is considered such a documented quality management system. The provisions of section 3.1. apply to the manufacturer's representative inasmuch as the manufacturer's representative, who is the holder of the type-approval, participates in the manufacture of the product and confirming the requirements relating to the conformity of the national type-approval to be granted.

According to section 3.2, the manufacturing process of the product must be controlled and managed by means of a quality management system. No substantive changes would be made to this section.

Subsection 3.2.1 would provide the minimum requirements for a quality management system.

Indent h of list item 6 would be amended to better reflect the documents required by that item. This requirement concerns the reports on previous conformity of production assessments.

List item 7 would be amended to include all possible eligible products in addition to vehicles by including all potential products falling within the scope of the CoP Regulation. There are no grounds for limiting this requirement to vehicles only.

The data processing procedure for the certificate of conformity (the 'CoC certificate') and the certificate's data would be added as a new list item 8 to subsection 3.2.1. The aim is that manufacturers should specify in greater detail, not only the processing procedure for the certificate of conformity but also the source of the information in the certificate. This requirement currently concerns EU and EC type-approval of vehicles and national small series type-approval. With regard to certificates of conformity, it should be noted that they are also subject, inter alia, to the provisions of indent c of list item 6 concerning external documents.

Linguistic amendments would be made to the wording of list item 11.

The provisions on the additional requirements for the quality management system regarding the duties, responsibilities and authority of persons involved in the manufacturing process of a type-approved product would be transferred to a new list item 13 to make the context more appropriate. The aim is to clarify the fact that the provision is as binding as the other factors in the list. The explicit requirement to define the human resources associated with the manufacture of a type-approved product would also be removed from the provision, since the requirement is materially included in the definition of the tasks, responsibilities and authority of the persons involved in the manufacturing process referred to in the new list item 13.

A linguistic amendment would be made to the reference in subsection 3.2.2. According to the section, the quality management system must include written control plans. This provision refers to the written control plans of products to be type-approved referred to later in the Regulation, in chapter 4.

According to subsection 3.2.3, the quality management system must be used to ensure components found to be unacceptable cannot be used in the manufacture of type-approved products and that products found to be unacceptable are not placed on the market. No substantive changes would be made to this section.

According to subsection 3.2.4, the quality management system must also specify and document how to ensure compliance of products placed on the market. The procedure is also applied to prior notifications for vehicles. The procedure must include a comparison between the data and requirements specified in the type-approval and the approval documentation. If the procedure is based on sampling, that must also be specified. No substantive changes would be made to this section.

In addition, according to subsection 3.2.5, the quality management system must include an audit programme, according to which internal audits are carried out. No substantive changes are made to this section.

If changes are made to the quality management system, subsection 3.2.6 requires that the changes are systematically implemented to ensure the continued conformity of products subject to type-approval. 'Systematic implementation' refers to a plan drafted in advance, and changes should not be made in the absence of an identifiable plan of changes.

The last paragraph of section 2.1 of the current Regulation would be numbered and become a new subsection 3.2.7. In the future, the section would also take into account the legal principles to be given in the Regulation in the future.

4 Written control plan

Section 3 of the Regulation is renumbered to create a new chapter 4, and technical amendments are also made to its sections. In the future, the provisions will be referred to by their number, which will be clearer. Each type-approved product must have a written control plan by means of which the manufacturer controls the conformity of the product during its manufacture and the placing on the market of the product. This document allows the manufacturer or the manufacturer's representative to indicate sufficient procedures for ensuring the conformity of production for a type-approved product as part of the quality management system. A reference to EC type-approval is added to the section.

According to section 4.1, the written control plan must include, inter alia, a description of the object under inspection. The description must include references to the mandatory legislation on the product and the relevant tests required under that legislation. In addition, where necessary, the parts of the structure of the product must be indicated in the description. The inspection method for an object refers to the manner

in which the inspection is carried out, such as a visual, written or physical inspection method. The frequency of inspection of an object refers to both the requirements under the law and the actual frequency. The details of the person responsible for the inspection and the procedure may be indicated, for example, by using the professional titles of the responsible parties within the organisation.

A new section 4.2 is added to the Regulation, which sets out further requirements for the content of the records of the written control plan. The reference to the information to be given on the result of the inspection and its justification under chapter 3, section 2, list item 5 of the current Regulation is also removed from the section because this reference is included in the records referred to in the new section 4.2. In the future, the provision will be duly included in what is laid down in subsection 4.2.2. The new subsection 4.2.2 includes a situation in which a written control plan also acts as a record.

Annex 1 to the Regulation would be deleted in order to avoid all ambiguity. In the future, the Finnish Transport and Communications Agency will publish examples of how to draw up a written control plan as separate support material. The examples are absent from the Regulation in order to avoid any doubt about its interpretation. In practice, the conditions involve case-by-case consideration, so a general example of the structure of a control plan is not directly applicable in such a way that it could be relied upon in the same way as a provision. The manufacturer must draw up a written control plan based on the product concerned and its production.

Chapter 4 on entry into force and transitional provisions will become a new chapter 5. The transitional provisions with a transitional period that has expired on the date of entry into force of the Regulation are deleted.

Entry into force of the Regulation

The Regulation is planned to enter into force in late summer/early autumn 2023.

Annexes

Summary of statements (if not included in the explanatory memorandum)
Comments (if drafted)