

Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (Text with EEA relevance)

CHAPTER XVI

DESIGNATION AND NOTIFICATION OF TECHNICAL SERVICES

Article 61

Requirements relating to technical services

1 Designating approval authorities shall ensure that before they designate a technical service pursuant to Article 63, that technical service meets the requirements laid down in paragraphs 2 to 9 of this Article.

2 Without prejudice to Article 64(1), a technical service shall be established under the national law of a Member State and have legal personality.

3 A technical service shall be a third-party body independent of the process of design, manufacturing, supply or maintenance of the vehicle, system, component or separate technical unit it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of vehicles, systems, components or separate technical units which it assesses, tests or inspects may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered as fulfilling the requirements of the first subparagraph.

4 A technical service, its top-level management and the personnel responsible for carrying out the categories of activities for which they are designated in accordance with Article 63(1) shall not be the designer, manufacturer, supplier, or maintainer of the vehicles, systems, components or separate technical units which they assess, nor represent parties engaged in those activities. This shall not preclude the use of assessed vehicles, systems, components or separate technical units referred to in paragraph 3 of this Article that are necessary for the operation of the technical service or the use of such vehicles, systems, components or separate technical units for personal purposes.

A technical service shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of the categories of activities for which it has been designated.

5 A technical service and its personnel shall carry out the categories of activities for which it has been designated with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their assessment activities, especially such pressures or inducements emanating from persons or groups of persons with an interest in the results of those activities.

6 A technical service shall be capable of carrying out all the categories of activities for which it has been designated in accordance with Article 63(1), by demonstrating to the satisfaction of its designating approval authority, that it has:

- a personnel with appropriate skills, specific technical knowledge and vocational training as well as sufficient and appropriate experience to perform the task;
- b descriptions of the procedures relevant for the categories of activities for which it is seeking to be designated, ensuring the transparency and reproducibility of those procedures;
- c procedures for the performance of the categories of activities for which it is seeking to be designated which take due account of the degree of complexity of the technology of the vehicle, system, component or separate technical unit in question, and the mass or serial nature of the production process; and
- d means necessary to perform in an appropriate manner the tasks connected with the categories of activities for which it is seeking to be designated and that it has access to all necessary equipment or facilities.

In addition, it shall demonstrate to the designating approval authority its compliance with the standards laid down in the delegated acts adopted pursuant to Article 65 which are relevant for the categories of activities for which it is designated.

7 The impartiality of the technical services, their top-level management and the assessment personnel shall be guaranteed. They shall not engage in any activity that may conflict with their independence of judgment or integrity in relation to the categories of activities for which they are designated.

8 Technical services shall take out liability insurance related to their activities unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

9 The personnel of a technical service shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation or any provision of national law giving effect to it, except in relation to the designating approval authority or where required by Union or national law. Proprietary rights shall be protected.

Article 62

Subsidiaries of and subcontracting by technical services

1 Technical services may subcontract some of their activities for which they have been designated in accordance with Article 63(1) or have those activities carried out by a subsidiary only with the agreement of their designating approval authority.

2 Where a technical service subcontracts specific tasks connected with the categories of activities for which it has been designated or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meet the requirements set out in Article 61 and shall inform the designating approval authority accordingly.

3 Technical services shall take full responsibility for the tasks performed by any of their subcontractors or subsidiaries, wherever these are established.

4 Technical services shall keep at the disposal of the designating approval authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the tasks performed by them.

Article 63

Designation of technical services

1 Technical services shall be designated for one or more of the following categories of activities, depending on their field of competence:

- a category A: technical services which carry out in their own facilities the tests referred to in this Regulation and in the acts listed in Annex II;
- b category B: technical services which supervise the tests referred to in this Regulation and in the acts listed in Annex II, where such tests are performed in the manufacturer's facilities or in the facilities of a third party;
- c category C: technical services which assess and monitor on a regular basis the manufacturer's procedures for controlling conformity of production;
- d category D: technical services which supervise or perform tests or inspections for the surveillance of conformity of production.

2 An approval authority may be designated as a technical service for one or more of the activities referred to in paragraph 1.

3 Technical services of a third country, other than those designated in accordance with Article 64, may be notified for the purposes of Article 67, but only if such an acceptance of technical services is provided for by a bilateral agreement between the Union and the third country concerned. This shall not prevent a technical service established under the national law of a Member State in accordance with Article 61(2) from establishing subsidiaries in third countries, provided that the subsidiaries are directly managed and controlled by the designated technical service.

Article 64

Accredited in-house technical services of the manufacturer

1 An accredited in-house technical service of a manufacturer may be designated only for category A activities with regard to technical requirements for which self-testing is allowed by a delegated act adopted pursuant to this Regulation. That technical service shall constitute a separate and distinct part of the undertaking and shall not be involved in the design, manufacturing, supply or maintenance of the vehicles, systems, components or separate technical units it assesses.

- 2 An accredited in-house technical service shall meet the following requirements:
- a in addition to being designated by the approval authority of a Member State it shall be accredited by a national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008 and in accordance with the standards and procedure referred to in Article 65 of this Regulation;
 - b the accredited in-house technical service and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which they form part which ensure their impartiality and demonstrate it to the relevant national accreditation body;
 - c neither the accredited in-house technical service nor its personnel shall engage in any activity that might conflict with their independence of judgment or integrity in relation to the categories of activities for which they have been designated;

- d the accredited in-house technical service shall supply its services exclusively to the undertaking of which it forms part.

3 An accredited in-house technical service need not be notified to the Commission for the purposes of Article 67, but information concerning its accreditation shall be given by the undertaking of which it forms part or by the national accreditation body to the designating approval authority at the request of that authority.

Article 65

Procedures for performance standards and assessment of technical services

In order to ensure that technical services meet the same high level of performance standards in all Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 75 concerning the standards with which the technical services have to comply and the procedure for their assessment in accordance with Article 66 and their accreditation in accordance with Article 64.

Article 66

Assessment of the skills of technical services

1 The designating approval authority shall draw up an assessment report demonstrating that the candidate technical service has been assessed for its compliance with the requirements of this Regulation and the delegated acts adopted pursuant to this Regulation. That report may include a certificate of accreditation issued by an accreditation body.

2 The assessment on which the report referred to in paragraph 1 is based shall be conducted in accordance with the provisions laid down in a delegated act adopted pursuant to Article 65. The assessment report shall be reviewed at least every three years.

3 The assessment report shall be communicated to the Commission upon request. In such cases, and where the assessment is not based on an accreditation certificate issued by a national accreditation body attesting that the technical service fulfils the requirements of this Regulation, the designating approval authority shall provide the Commission with documentary evidence which attests the technical service's competence and the arrangements in place to ensure that the technical service is monitored regularly by the designating approval authority and satisfies the requirements of this Regulation and the delegated acts adopted pursuant to this Regulation.

The approval authority that intends to be designated as a technical service in accordance with Article 63(2) shall document compliance through an assessment conducted by auditors independent of the activity being assessed. Such auditors may be from the same organisation provided that they are managed separately from personnel undertaking the assessed activity.

4 An accredited in-house technical service shall comply with the relevant provisions of this Article.

Article 67

Procedures for notification

1 Member States shall notify to the Commission the name, the address including electronic address, the responsible persons and the category of activities with respect to each technical service they have designated, as well as any subsequent modifications to those designations. The notification shall state for which subjects listed in Annex II the technical services have been designated.

2 A technical service may conduct the activities referred to in Article 63(1) on behalf of the designating approval authority responsible for the type-approval only if it has been notified beforehand to the Commission in accordance with paragraph 1 of this Article.

3 The same technical service may be designated by several designating approval authorities and notified by the Member States of these designating approval authorities, irrespective of the category or categories of activities it will conduct in accordance with Article 63(1).

4 The Commission shall be notified of any subsequent relevant changes to the designation.

5 Where a specific organisation or competent body carrying out an activity not included in those referred to in Article 63(1) needs to be designated in application of an act listed in Annex II, the notification shall be made in accordance with this Article.

6 The Commission shall publish on its website a list and details of the technical services notified in accordance with this Article.

Article 68

Changes to designations

1 Where a designating approval authority has ascertained or has been informed that a technical service designated by it no longer meets the requirements laid down in this Regulation, or that it is failing to fulfil its obligations, the designating approval authority shall restrict, suspend or withdraw the designation as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. The Member State that has notified this technical service shall immediately inform the Commission accordingly. The Commission shall modify the information published referred to in Article 67(6) accordingly.

2 In the event of restriction, suspension or withdrawal of the designation, or where the technical service has ceased its activity, the designating approval authority shall take appropriate steps to ensure that the files of that technical service are either processed by another technical service or kept available for the designating approval authority or for the market surveillance authorities at their request.

Article 69

Challenge to the competence of technical services

1 The Commission shall investigate all cases where it has doubts, or doubt is brought to its attention, regarding the competence of a technical service or the continued fulfilment by a technical service of the requirements and responsibilities to which it is subject.

2 The Member State of the designating approval authority shall provide the Commission, on request, with all information relating to the basis for the designation or the maintenance of the designation of the technical service concerned.

3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 Where the Commission ascertains that a technical service does not meet or no longer meets the requirements for its designation, it shall inform the Member State of the designating approval authority accordingly, with a view to establishing, in cooperation with that Member State, the corrective measures necessary, and shall request that Member State to take those corrective measures, including the withdrawal of the designation if necessary.

Article 70

Operational obligations of technical services

1 Technical services shall carry out the categories of activities for which they have been designated on behalf of the designating approval authority and in accordance with the assessment and test procedures provided for in this Regulation and the acts listed in Annex II.

Technical services shall supervise or shall themselves carry out the tests required for approval or inspections as set out in this Regulation or in one of the acts listed in Annex II, except where alternative procedures are permitted. The technical services shall not conduct tests, assessments or inspections for which they have not been duly designated by their approval authority.

2 Technical services shall at all times:

- a allow their designating approval authority to witness the technical service during the conformity assessment as appropriate; and
- b without prejudice to Article 61(9) and Article 71, provide their designating approval authority such information on their categories of activities falling under the scope of this Regulation as may be requested.

3 Where a technical service finds that requirements laid down in this Regulation have not been met by a manufacturer, it shall report this to the designating approval authority with a view for the designating approval authority requiring the manufacturer to take appropriate corrective measures and subsequently not to issue a type-approval certificate unless the appropriate corrective measures have been taken to the satisfaction of the approval authority.

4 Where, in the course of monitoring conformity of production following the issue of a type-approval certificate, a technical service acting on behalf of the designating approval authority finds that a vehicle, system, component or separate technical unit no longer complies with this Regulation, it shall report this to the designating approval authority. The approval authority shall take the appropriate measures as provided for in Article 33.

Article 71

Information obligations of technical services

- 1 Technical services shall inform their designating approval authority of the following:
 - a any non-conformity encountered which may require a refusal, restriction, suspension or withdrawal of a type-approval certificate;
 - b any circumstances affecting the scope of and conditions for their designation;
 - c any request for information which they have received from market surveillance authorities regarding their activities.
- 2 On request from their designating approval authority, technical services shall provide information on the activities within the scope of their designation and on any other activity performed, including cross-border activities and subcontracting.