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Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (Text with EEA relevance)

CHAPTER XV

ASSESSMENT, DESIGNATION, NOTIFICATION AND MONITORING OF TECHNICAL SERVICES

Article 67

Type-approval authority responsible for technical services

- The approval authority designated by the Member State in accordance with Article 6(2), (referred to for the purposes of this Chapter as the 'type-approval authority'), shall be responsible for the assessment, designation, notification and monitoring of technical services, including, where appropriate, the subcontractors or subsidiaries of those technical services. The type-approval authority may decide that the assessment and monitoring of technical services and, where appropriate, of the subcontractors or subsidiaries of those technical services, is to be carried out by a national accreditation body.
- 2 Type-approval authorities shall be subject to peer evaluations in respect of any activity which they carry out related to the assessment and monitoring of technical services.

Peer evaluations shall cover the assessments of the entire or partial operations of technical services that have been carried out by type-approval authorities in accordance with Article 73(4), including the competence of the personnel, the correctness of the test and inspection methodology and the correctness of test results based on a defined scope of regulatory acts listed in Part I of Annex II.

Activities related to the assessment and monitoring of technical services that only deal with national individual approvals that were granted in accordance with Article 45 or with national type-approvals of vehicles produced in small series that were granted in accordance with Article 42 are exempted from peer evaluations

Any assessment of accredited technical services by type-approval authorities shall be exempt from peer evaluations.

- 3 Type-approval authorities shall not be subject to peer evaluations when they designate all their technical services exclusively on the basis of accreditation of the technical services.
- 4 The type-approval authority shall not provide consultancy services on a commercial or competitive basis.
- 5 The type-approval authority shall have a sufficient personnel at its disposal to carry out the tasks laid down in this Regulation.
- 6 Each Member State shall provide the Commission, the Forum and other Member States that so request with information on its procedures for the assessment, designation

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and notification of technical services and for the monitoring of technical services, and of any changes to the procedures.

The Commission may adopt implementing acts laying down the model for the provision of information on the procedures of the Member States referred to in the first subparagraph of this paragraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(2).

- Type-approval authorities that are subject to peer-evaluations shall establish procedures for internal audits in accordance with Appendix 2 of Annex III. Such internal audits shall be performed at least once a year. However, the frequency of internal audits may be reduced if the type-approval authority can demonstrate that its management system is being implemented effectively and has proven stability.
- 8 Peer-evaluations of a type-approval authority shall be carried out at least once every five years by a peer-evaluation team, composed of two type-approval authorities from other Member States.

The Commission may decide to participate in the peer-evaluation team on the basis of a risk assessment analysis.

The peer-evaluation shall be carried out under the responsibility of the approval authority that is subject to evaluation, and shall include a visit to the premises of a technical service selected at the discretion of the peer-evaluation team.

Type-approval authorities that are not subject to peer-evaluation in accordance with paragraph 3 shall not be included in any of the activities related to the peer-evaluation team

- Taking duly into account the considerations of the Forum, the Commission may adopt implementing acts setting out a plan for peer-evaluations covering a period of at least five years, laying down criteria concerning the composition of the peer-evaluation team, the methodology used for the peer-evaluation, the schedule, periodicity and the other tasks related to the peer-evaluation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(2).
- The outcome of the peer evaluations shall be examined by the Forum. The Commission shall draw up summaries of the outcome of peer evaluations and make them public.

Article 68

Designation of technical services

- 1 The type-approval authorities shall designate technical services for one or more of the following categories of activities, depending on their field of competence:
 - a category A: tests referred to in this Regulation and in the regulatory acts listed in Annex II that technical services carry out in their own facilities;
 - b category B: the supervision of the tests, which includes test preparation, referred to in this Regulation and in the regulatory acts listed in Annex II, where such tests are performed at the manufacturer's facilities or at the facilities of a third party;
 - c category C: the assessment and monitoring on a regular basis of the procedures of the manufacturer for controlling the conformity of production;
 - d category D: the supervision or performance of tests or inspections for the surveillance of the conformity of production.

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- 2 Each Member State may designate a type-approval authority as a technical service for one or more of the categories of activities referred to in paragraph 1.
- A technical service shall be established under the law of a Member State and have legal personality, except for a technical service belonging to a type-approval authority and except for an accredited in-house technical service of the manufacturer, as referred to in Article 72.
- A technical service shall take out liability insurance for its activities, unless such liability is assumed by its Member State in accordance with national law, or unless the Member State itself is directly responsible for the conformity assessment.
- Technical services of a third country, other than those that have been designated in accordance with Article 72, may only be designated and may only be notified to the Commission for the purposes of Article 74 where a bilateral agreement between the Union and the third country concerned provides for the possibility of designating such technical services. This shall not prevent a technical service that is established under the law of a Member State in accordance with paragraph 3 of this Article from establishing subsidiaries in third countries, provided that those subsidiaries are directly managed and controlled by the designated technical service.

Article 69

Independence of the technical services

- A technical service, including its personnel, shall be independent and shall carry out the activities for which it has been designated with the highest degree of professional integrity and the requisite technical competence in the specific field in which it operates and shall be free from all pressures and inducements, particularly financial, that might influence its judgment or the results of its assessment activities, in particular such pressures or inducements emanating from persons or groups of persons with an interest in the results of those activities.
- 2 Technical services shall be third-party organisation or body that is not involved in the process of the design, manufacturing, supply or maintenance of the vehicle, system, component or separate technical unit that it assesses, tests or inspects.

An organisation or body that belongs to a trade association or to a professional federation representing undertakings that are involved in the design, manufacturing, supply or maintenance of the vehicles, systems, components or separate technical units that it assesses, tests or inspects, may be considered as fulfilling the requirements of the first subparagraph, provided that its independence and the absence of any conflict of interest are demonstrated to the type-approval authority of the relevant Member State.

- A technical service, its top-level management and the personnel responsible for carrying out the activities for which they are designated in accordance with Article 68(1) shall not design, manufacture, supply, or maintain the vehicles, systems, components or separate technical units that they assess, nor represent parties engaged in those activities. This shall not preclude the use of those vehicles, systems, components or separate technical units 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.
- 4 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 The personnel of a technical service shall observe professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation, except in relation

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to the type-approval authority and, where relevant, to the national accreditation body, or where required by Union or national law.

Article 70

Competence of the technical services

- 1 A technical service shall be capable of carrying out all the activities for which it is applying to be designated in accordance with Article 68(1). It shall demonstrate to the type-approval authority or to the national accreditation body carrying out the assessment or monitoring of that technical service that it satisfies all of the following conditions:
 - a its personnel have the appropriate skills, the specific technical knowledge, the vocational training and sufficient and appropriate experience to perform the activities for which it is applying to be designated;
 - b it possesses descriptions of the procedures relevant for the performance of the activities for which it is applying to be designated, taking due account of the degree of complexity of the technology of the relevant vehicle, system, component or separate technical unit in question, as well as the mass or serial nature of the production process. The technical service shall demonstrate the transparency and reproducibility of those procedures;
 - c it has the necessary means to perform the tasks connected with the category or categories of activities for which it is applying to be designated, and it has access to all necessary equipment or facilities.
- A technical service shall also demonstrate that it has the appropriate skills, the specific technical knowledge and proven experience to carry out tests and inspections for assessing the conformity of the vehicles, systems, components and separate technical units with this Regulation and shall demonstrate its compliance with the standards listed in Appendix 1 to Annex III. However, the standards listed in Appendix 1 to Annex III do not apply for the purposes of the last stage of a national multi-stage procedure referred to in Article 47(1).
- 3 The Commission is empowered to adopt delegated acts in accordance with Article 82, amending Annex III as regards the requirements for the assessment of the technical services.

Article 71

Subsidiaries of and subcontracting by technical services

- 1 Technical services may subcontract, with the agreement of the designating typeapproval authority, some of the categories of activities for which they have been designated in accordance with Article 68(1), or have those activities carried out by a subsidiary.
- Where a technical service subcontracts specific tasks within the categories of activities for which it has been designated or has a subsidiary perform those tasks, it shall ensure that the subcontractor or the subsidiary complies with the requirements set out in Articles 68, 69 and 70 and shall inform the type-approval authority thereof.
- 3 Technical services shall take full responsibility for the tasks performed by their subcontractors or subsidiaries, regardless of their place of establishment.
- 4 Technical services shall keep at the disposal of the designating type-approval authority the relevant documents concerning the assessment carried out by the type-approval authority or the accreditation carried out by the national accreditation body of the subcontractor or the subsidiary and the tasks performed by them.

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Article 72

In-house technical service of the manufacturer

- An in-house technical service of a manufacturer may be designated as a technical service for activities under category A as referred to in point (a) of Article 68(1), and only with regard to the regulatory acts listed in Annex VII. An in-house technical service shall constitute a separate and distinct part of the manufacturer's company and shall not be involved in the design, manufacturing, supply or maintenance of the vehicles, systems, components or separate technical units that it assesses.
- 2 An in-house technical service referred to in paragraph 1 shall comply with the following requirements:
 - a it has been accredited by a national accreditation body and complies with the requirements laid down in Appendices 1 and 2 to Annex III;
 - b the in-house technical service, including its personnel, is organisationally identifiable and has reporting methods within the manufacturer's company of which they form part that ensures its impartiality and demonstrates that impartiality to the relevant type-approval authority and to the national accreditation body;
 - c neither the in-house technical service nor its personnel is engaged in any activity that might conflict with its independence or with its integrity to perform the activities for which it has been designated;
 - d it supplies its services only to the manufacturer's company of which it forms part.
- 3 The Commission is empowered to adopt delegated acts in accordance with Article 82, amending Annex VII to take account of technical and regulatory developments by updating the list of regulatory acts and restrictions contained therein.

Article 73

Assessment and designation of technical services

- 1 The applicant technical service shall submit a formal application to the type-approval authority of the Member State in which it requests to be designated in accordance with point 4 of Appendix 2 to Annex III. The application shall specify the categories of the activities for which the technical service is applying to be designated.
- Before a type-approval authority designates a technical service, the type-approval authority or the national accreditation body shall assess it in accordance with an assessment check-list that covers at least the requirements laid down in Appendix 2 to Annex III. The assessment shall include an on-site assessment in the premises of the applicant technical service, and, where relevant, of any subsidiary or sub-contractor, whether located inside or outside the Union.
- In cases where the assessment is carried out by a national accreditation body, the applicant technical service shall deliver to the type-approval authority a valid accreditation certificate and the corresponding assessment report attesting that the technical service fulfils the requirements laid down in Appendix 2 to Annex III for the categories of activities for which the applicant technical service is applying to be designated.
- 4 In cases where the assessment is carried out by the type-approval authority, the type-approval authority of the Member State from which the applicant technical service has requested

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to be designated shall formally appoint a joint assessment team composed of representatives of the type-approval authorities of at least two other Member States and a representative of the Commission.

Where the technical service applies to be designated in a Member State other than the Member State of its establishment, one of the representatives of the joint assessment team shall be from the type-approval authority of the Member State of its establishment, unless that type-approval authority decides against participating in the joint assessment team.

The joint assessment team shall participate in the assessment of the applicant technical service, including the on-site assessment. The designating type-approval authority of the Member State in which the applicant technical service has requested to be designated shall give the joint assessment team all necessary assistance and provide timely access to all documentation necessary to assess the applicant technical service.

- In cases where the assessment is carried out by the type-approval authority that designates technical services which apply to perform tests exclusively for national individual vehicle approvals in accordance with Article 45, the type-approval authority of the Member State in which the applicant technical service has requested to be designated shall be exempt from the obligation to appoint a joint assessment team. The technical services which are only checking the correct installation of components on categories O_1 and O_2 shall also be exempt from assessment.
- If the technical service has requested to be designated by one or more type-approval authorities from Member States other than the Member State of its establishment in accordance with Article 74(2), the assessment shall be carried out only once, provided that the entire scope of the technical service's designation has been covered in that assessment.
- The joint assessment team shall raise findings regarding non-compliance of the applicant technical service with the requirements laid down in Articles 68 to 72, in Articles 80 and 81 and in Appendix 2 to Annex III during the assessment process. Such findings shall be discussed within the joint assessment team.
- 8 The joint assessment team shall produce after the on-site assessment a report setting out the extent to which the applicant technical service complies with the requirements laid down in Articles 68 to 72, in Articles 80 and 81 and in Appendix 2 to Annex III.
- 9 The report referred to in paragraph 8 shall contain a summary of any identified noncompliances, together with a recommendation as to whether the applicant may be designated as technical service.
- The type-approval authority shall notify to the Commission the names and the expertise of their representatives who are to participate in each joint assessment team.
- The type-approval authority of the Member State where the applicant technical service has requested to be designated shall send the report on the outcome of the assessment in accordance with the procedures laid down in Appendix 2 to Annex III, to the Commission and, upon request, to the type-approval authorities of the other Member States. That report shall include documentary evidence regarding the competence of the technical service and the arrangements that the type-approval authority has in place to regularly monitor the technical service.
- The type-approval authorities of the other Member States and the Commission may review the assessment report and the documentary evidence, raise questions or concerns and

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request further documentary evidence within one month from the date of reception of the assessment report and the documentary evidence.

- The type-approval authority of the Member State where the applicant technical service has requested to be designated shall respond to the questions, concerns and requests for further documentary evidence within four weeks following their receipt.
- Within four weeks following the receipt of the response referred to in paragraph 13, the type-approval authorities of the other Member States or the Commission may individually or jointly address recommendations to the type-approval authority of the Member State where the applicant technical service has requested to be designated. That type-approval authority shall take account of the recommendations when it takes the decision on the designation of the technical service. Where that type-approval authority decides not to follow the recommendations addressed by the other Member States or the Commission, it shall give the reasons therefor within two weeks after taking its decision.
- The validity of the designation of technical services shall be limited to five years.
- The type-approval authority that intends to be designated as a technical service in accordance with Article 68(2) shall document compliance with this Regulation through an assessment conducted by independent auditors. Those auditors may be from within the same organisation provided that they are managed autonomously from the personnel undertaking the assessed activity, and provided that they comply with the requirements laid down in Appendix 2 to Annex III.

Article 74

Notification to the Commission concerning designation of technical services

The type-approval authorities shall notify to the Commission the name, the address, including the electronic address, the responsible persons and the category of activities of every technical service that they have designated. The notification shall clearly specify the scope of the designation, the conformity assessment activities and procedures, the type of vehicles, systems, components and separate technical units, and the subjects listed in Annex II, for which the technical services have been designated, as well as any subcontractors or subsidiaries of the technical services, and any subsequent modifications to any of those details.

Such notification shall be made before the designated technical service concerned conducts any activity referred to in Article 68(1).

- A technical service may be designated by one or more type-approval authorities of Member States other than the Member State of its establishment, provided that the entire scope of the designation by the type-approval authority is covered by an accreditation issued in accordance with Article 73(3), or by an assessment carried out in accordance with Article 73(4).
- The Commission shall publish on its website, and keep up-to-date, a list with contact details of the designated technical services, their subcontractors and their subsidiaries that have been notified to it in accordance with this Article.

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Article 75

Changes to and renewal of designations of technical services

Where the type-approval authority has ascertained or has been informed that a technical service no longer complies with the requirements laid down in this Regulation, that type-approval authority shall restrict, suspend or withdraw the designation, as appropriate, depending on the seriousness of the failure to comply with those requirements.

The type-approval authority shall immediately notify to the Commission and the type-approval authorities of the other Member States any restriction, suspension or withdrawal of a designation.

The Commission shall update the list referred to in Article 74(3) accordingly.

- In the event of a restriction, suspension or withdrawal of the designation, or where the technical service has ceased its activity, the type-approval authority shall keep the files of that technical service available for the approval authorities or for the market surveillance authorities or transfer those files to another technical service chosen by the manufacturer in agreement with that technical service.
- 3 The type-approval authority shall assess within three months of the notification referred to in the second subparagraph of paragraph 1 whether the non-compliance of the technical service has an impact on EU type-approval certificates issued on the basis of the inspection and test reports issued by the technical service subject of the change in designation and inform the other type-approval authorities and the Commission accordingly.

Within two months after having notified the changes to the designation, the type-approval authority shall submit a report on its findings regarding the non-compliance to the Commission and the other type-approval authorities. Where necessary to ensure the safety of vehicles, systems, components or separate technical units already placed on the market, the designating type-approval authority shall instruct the type-approval authorities concerned to suspend or withdraw within a reasonable period of time, any EU type-approval certificates which were unduly issued.

- Where the designation of technical services has been restricted, suspended or withdrawn, the EU type-approval certificates which were issued on the basis of inspection and test reports issued by those technical services shall remain valid unless those type-approvals become invalid in accordance with point (f) of Article 35(2).
- 5 Extensions of the scope of the technical service's designation that lead to the designation of an additional category of activities referred to in Article 68(1) shall be assessed in accordance with the procedure set out in Article 73.

Extensions of the scope of a technical service's designation only for the regulatory acts listed in Annex II may be carried out in accordance with the procedures laid down in Appendix 2 to Annex III, and subject to the notification referred to in Article 74.

The designation of a technical service shall only be renewed after the type-approval authority has verified that the technical service continues to comply with the requirements of this Regulation. That assessment shall be carried out in accordance with the procedure set out in Article 73.

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Article 76

Monitoring of technical services

The designating type-approval authority shall continuously monitor the technical services to ensure compliance with the requirements laid down in Articles 68 to 72, in Articles 80 and 81 and in Appendix 2 to Annex III.

The first subparagraph of this paragraph shall not apply to any activities of technical services which are monitored by accreditation bodies in accordance with Article 67(1) for the purposes of ensuring compliance with the requirements laid down in Articles 68 to 72, in Articles 80 and 81 and in Appendix 2 to Annex III.

Technical services shall supply on request all relevant information and documents that are required to enable the designating type-approval authority or national accreditation body to verify compliance with those requirements.

Technical services shall inform the designating type-approval authority or national accreditation body without delay of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors, which may affect compliance with the requirements set out in Articles 68 to 72, in Articles 80 and 81 and in Appendix 2 to Annex III, or their ability to perform the conformity assessment tasks relating to the vehicles, systems, components and separate technical units for which they have been designated.

- 2 Technical services shall respond without delay to requests by a type-approval authority or by the Commission in relation to the conformity assessments they have carried out.
- The designating type-approval authority shall ensure that the technical service carries out its obligation laid down in paragraph 2 of this Article, unless there is a legitimate reason for not doing so.

Where that type-approval authority acknowledges a legitimate reason, it shall inform the Commission thereof.

The Commission shall consult the Member States without delay. On the basis of that consultation, the Commission shall adopt implementing acts to decide if the legitimate reason is justified or not. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(2).

The technical service and the designating type-approval authority may request that any information that is transmitted to the type-approval authority of another Member State or to the Commission shall be treated confidentially.

At least every 30 months, the designating type-approval authority shall assess whether each technical service under its responsibility continues to satisfy the requirements set out in Articles 68 to 72, in Articles 80 and 81 and in Appendix 2 to Annex III. That assessment shall include an on-site assessment of each technical service under its responsibility.

Within two months after finalising the assessment of the technical service, each Member State shall report to the Commission and to the other Member States on its monitoring activities. Those reports shall contain a summary of the assessment, which shall be made publicly available.

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Article 77

Challenge to the competence of technical services

The Commission, in cooperation with the type-approval authority of the Member State concerned, shall investigate all cases where concerns have been brought to its attention regarding the competence of a technical service or the continued compliance by a technical service with the requirements and responsibilities to which it is subject under this Regulation. The Commission may also commence such investigations on its own initiative.

The Commission shall investigate the responsibility of the technical service in the case where it is demonstrated or where there are justified grounds for considering that a type-approval has been granted on the basis of false data, that the test results have been falsified or that data or technical specifications have been withheld that would have led to the refusal to grant the type-approval.

- The Commission shall consult the designating type-approval authority, as part of the investigation referred to in paragraph 1. That type-approval authority shall provide the Commission, upon request, with all relevant information relating to the performance and the compliance with the requirements concerning independence and competence of the technical service concerned.
- 3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
- Where the Commission ascertains that a technical service does not comply or no longer complies with the requirements for its designation, or that it is responsible for any of the situations referred to in paragraph 1, it shall inform the Member State of the designating type-approval authority thereof.

The Commission shall request that Member State to take restrictive measures, including the restriction, suspension or withdrawal of the designation, where necessary.

Where a Member State fails to take the necessary restrictive measures, the Commission may adopt implementing acts to decide to restrict, suspend or withdraw the designation of the technical service concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(2). The Commission shall notify the Member State concerned of those implementing acts and shall update the information published referred to in Article 74(3) accordingly.

Article 78

Exchange of information on assessment, designation and monitoring of technical services

- Type-approval authorities shall consult each other and the Commission on questions with general relevance with regard to the implementation of the requirements set out in this Regulation in relation with the assessment, designation and monitoring of technical services.
- Type-approval authorities shall communicate to each other and the Commission the model for the assessment check-list used in accordance with Article 73(2) by 5 July 2020 and, thereafter, the adaptations made to that check-list, until the Commission has adopted a harmonised assessment check-list. The Commission is empowered to adopt implementing acts

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to establish the template of the harmonised assessment check-list. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 83(2).

Where the assessment reports referred to in Article 73(8) indicate discrepancies in the general practice of type-approval authorities, Member States or the Commission may request an exchange of information.

The exchange of information shall be coordinated by the Forum.

Article 79

Cooperation with national accreditation bodies

- Where the designation of a technical service is based on accreditation within the meaning of Regulation (EC) No 765/2008, the national accreditation body and the type-approval authority shall fully cooperate and shall exchange relevant information in compliance with Regulation (EC) No 765/2008, including incident reports and other information that relate to matters under the control of the technical service when that information is relevant for the assessment of the performance of the technical service.
- Member States shall ensure that type-approval authority of the Member State in which the technical service is established keeps the national accreditation body in charge of the accreditation of a particular technical service informed of any findings that are relevant to the accreditation. The national accreditation body shall inform the type-approval authority of the Member State in which the technical service is established of its findings.

Article 80

Operational obligations of technical services

- 1 Technical services shall carry out the activities for which they have been designated in accordance with Article 68(1).
- 2 At all times, technical services shall:
 - a allow the designating type-approval authority to witness the performance of the technical service during testing for type-approval; and
 - b where requested, provide the designating type-approval authority with information on the categories of activities for which they have been designated.
- Where a technical service finds that a manufacturer does not comply with the requirements laid down in this Regulation, it shall report this non-compliance to the type-approval authority in order for that type-approval authority to require the manufacturer to take appropriate corrective measures. The type-approval authority shall refuse to issue a type-approval certificate where those appropriate corrective measures have not been taken.

Article 81

Information obligations of technical services

1 Technical services shall inform the designating type-approval authority of the following:

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- a any non-conformity encountered which may require the 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 Upon request from the designating type-approval authority, technical services shall provide information on the activities within the scope of their designation or on any other activity they have performed, including cross-border activities and subcontracting.

Status:

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Changes to legislation:

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