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)

REGULATION (EU) 2018/858 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 30 May 2018

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) In accordance with Article 26(2) of the Treaty on the Functioning of the European Union (TFEU), the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is to be ensured. Internal market rules should be transparent, simple, consistent and effective, thereby providing legal certainty and clarity for the benefit of businesses and consumers.

(2) To that end, a comprehensive EU framework for the approval of motor vehicles and their trailers, and of the systems, components and separate technical units intended for such vehicles, was established by Directive 2007/46/EC of the European Parliament and of the Council[(3)].

(3) In 2013, the Commission carried out an assessment of the Union legal framework for the type-approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles which showed that the framework established by Directive 2007/46/EC is appropriate for achieving the main goals of harmonisation, effective functioning of the internal market and fair competition, and concluded that it should therefore continue to apply.

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(4) That assessment also concluded, however, that there is a need to introduce market surveillance provisions to complement the type-approval requirements; a need to clarify the recall and safeguard procedures, as well as the conditions for granting extensions to approvals for existing types of vehicle; a need to improve the enforcement of the framework for type-approval by harmonising and enhancing the type-approval procedures and conformity of production procedures applied by Member States' authorities and technical services; a need to clearly delineate the roles and responsibilities of economic operators in the supply chain, and of the authorities and parties involved in the enforcement of the framework, guaranteeing the independence of those authorities and parties, and preventing conflicts of interest; and a need to improve the suitability of alternative approval schemes (national small series and individual vehicle approvals) and the suitability of the multi-stage type-approval process to provide appropriate flexibility for niche markets and small and medium-sized enterprises without, however, distorting the level playing field.

(5) In addition, recent problems with the implementation of the framework for EU type-approval have revealed particular weaknesses and have demonstrated the need for its fundamental revision in order to ensure that it is robust, transparent, predictable and sustainable and that it provides a high level of safety and of health and environmental protection.

(6) This Regulation introduces a number of safeguards to prevent requirements imposed in the process of granting approval to vehicles, systems, components or separate technical units from being misapplied. In order to prevent abuse of the approval process in the future, it is important that those safeguards are effective.

(7) This Regulation lays down harmonised rules and principles for the type-approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, and for individual vehicle approval, with a view to ensuring the proper functioning of the internal market for the benefit of businesses and consumers and in order to offer a high level of safety and of health and environmental protection.

(8) This Regulation lays down the technical and administrative type-approval requirements for motor vehicles for the carriage of passengers (category M), and motor vehicles for the carriage of goods (category N) and their trailers (category O), and for the systems, components and separate technical units intended for such vehicles with a view to ensuring a high level of safety and of environmental performance.

(9) National authorities should apply and enforce the requirements of this Regulation in a uniform manner across the Union to ensure a level playing field and to avoid divergent standards being applied across the Union. They should fully cooperate with the Forum for Exchange of Information on Enforcement (‘the Forum’) and with the Commission in its audit and oversight activities.

(10) This Regulation should strengthen the current framework for EU type-approval, in particular through the introduction of provisions on market surveillance. Market surveillance in the automotive sector should be introduced by specifying the obligations

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of the economic operators in the supply chain, the responsibilities of the enforcement authorities in the Member States, and the measures to be taken when automotive products are encountered on the market that represent serious safety or environmental risks, that undermine the protection of consumers, or that do not comply with the type-approval requirements.

(11) In order to ensure an effective implementation of the type-approval requirements, the current provisions on conformity of production should be enhanced by, *inter alia*, providing for mandatory periodic audits of the conformity control methods and of the continued conformity of the automotive products concerned and, by reinforcing the requirements relating to the competence, obligations and performance of the technical services that carry out tests for whole-vehicle type-approval under the responsibility of approval authorities. The proper functioning of technical services is crucial for ensuring a high level of safety and of environmental protection and citizens' confidence in the system. The criteria for designation of technical services provided by Directive 2007/46/EC should be laid down in this Regulation in greater detail in order to ensure that they are applied consistently in all Member States. The assessment methods of the technical services in Member States have a tendency to differ progressively due to the increased complexity of their work. Therefore, it is necessary to provide for procedural obligations that ensure an exchange of information, and monitoring of Member States' practices for, the assessment, designation, notification and monitoring of their technical services. Those procedural obligations should remove any existing discrepancies in the methods used by, and in the interpretation of the criteria for the designation of, technical services. In order to ensure adequate oversight and a level playing-field across the Union, the assessment of an applicant technical service should include an on-site assessment.

(12) In the case of multi-stage type-approvals, it is essential to verify that changes made before the final stage of completion do not affect the functioning of type-approved systems, components or separate technical units in a way that would invalidate the type-approval previously granted.

(13) The need for control and monitoring of technical services has increased because technical progress has increased the risk of technical services not possessing the necessary competence to test new technologies or devices that emerge within their scope of designation. As technical progress shortens product cycles and as the intervals of surveillance on-site assessments and of the monitoring vary, the validity of the designation of technical services should be limited in time, which should ensure that the competence of technical services is periodically assessed.

(14) The designation and monitoring of technical services by the Member States, in accordance with detailed and strict criteria, should therefore be subject to supervisory controls, *inter alia* as a condition for the renewal of their designation. The position of technical services vis-à-vis manufacturers should be strengthened, including their right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on automotive products covered by this Regulation, in order to ensure

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continuous compliance by manufacturers after they have obtained a type-approval for their automotive products.

(15) In order to increase transparency and mutual trust and to further align and develop the criteria for the assessment, designation, and notification of technical services, as well as extension and renewal procedures, Member States should cooperate with each other and with the Commission. Member States should consult each other and the Commission on questions with general relevance for the implementation of this Regulation and inform each other and the Commission. It is important that the Member States and the Commission use a common secure electronic exchange system as a means to facilitate and enhance administrative cooperation after appropriate implementation periods in order to make managing the exchange of information more efficient and effective on the basis of simple and unified procedures. In order to facilitate its accessibility and transparency, information should be available as structured data that is electronically searchable.

(16) Where designation of a technical service is based on accreditation within the meaning of Regulation (EC) No 765/2008 of the European Parliament and of the Council[(4)], accreditation bodies and designating approval authorities should exchange information relevant for the assessment of the competence of technical services.

(17) The Member States should have the possibility to levy fees for the designation and monitoring of technical services in order to ensure the sustainability of the monitoring of those technical services by Member States and to establish a level playing field for technical services.

(18) When, in spite of the measures taken by the Member States to ensure a coherent and continuing application of the requirements, the competence of a technical service is in doubt, the Commission should have the possibility to investigate individual cases.

(19) In order to ensure that tests and reports provided by technical services are not influenced by non-legitimate circumstances, it is important that the organisation and operation of technical services ensure full impartiality and independence. To be able to carry out their tasks in a coherent and systematic manner, technical services should have in place a satisfactory management system that includes provisions on professional secrecy. In order to allow technical services to perform their work properly, their personnel should always exhibit the appropriate level of knowledge, competence and independence.

(20) A robust compliance enforcement mechanism is necessary in order to ensure that the requirements under this Regulation are met. Ensuring compliance with the type-approval and conformity of production requirements of the legislation governing the automotive sector should remain the key responsibility of the approval authorities, as it is an obligation closely linked to the issuing of the type-approval and requires detailed knowledge of its content. It is therefore important that the performance of approval authorities is regularly verified.

(21) In order to ensure compliance with this Regulation, to ensure its uniform application within the Union and to facilitate an exchange of best practices, the Commission should organise and carry out assessments of the procedures set up by approval authorities

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in accordance with this Regulation. The outcome of such assessments, including any non-binding recommendations, should be discussed within the Forum. The assessments should be carried out periodically, taking into account the principle of proportionality, the number and variety of type-approvals granted and any instances of non-compliance discovered during the compliance verification.

(22) In order to ensure the effectiveness of the Commission's assessment while minimising the administrative burden, it is important that the approval authorities and the Commission cooperate efficiently during the assessment, in particular during the assessment at the premises of the approval authority concerned. The Commission assessments should be carried out in compliance with applicable law, complying, *inter alia*, with the working periods or language of the national authorities. The costs arising from those assessments should be borne by the Commission, including those related to document translation.

(23) The compliance verification system is being strengthened by the recognition of a formal process of accreditation of technical services or via the introduction of regular peer-evaluation in respect of the assessment and monitoring of technical services by approval authorities. This aims to ensure that a uniform level of quality and stringency is applied by all approval authorities in enforcing the type-approval requirements.

(24) Closer coordination between national authorities through information exchange and coordinated assessments under the direction of a coordinating authority is fundamental in order to ensure a consistently high level of safety and of health and environmental protection within the internal market. It would also lead to more efficient use of scarce resources at national level. For this purpose, an advisory Forum should be established for Member States and the Commission with the objective of promoting best practices, exchanging information and coordinating activities related to the enforcement of type-approval legislation. The currently informal cooperation between Member States in that respect would benefit from a more formal framework. The Forum should be composed of representatives appointed by the Member States representing their approval authorities and market surveillance authorities. The representatives attending a given meeting should be selected on the basis of the issues discussed by the Forum. In order to benefit from a range of views and inputs, it is useful for particular outside observers to be invited on a regular basis to the Forum, whenever those observers' activities are relevant to the issues to be discussed.

(25) In order to avoid potential conflicts of interest, approval authorities and market surveillance authorities should not be linked when carrying out their tasks. Where a Member State chooses to place those authorities within the same organisation, it should at least ensure that that organisation has structures that ensure that the activities of the authorities remain distinct from one another in terms of their direct management and decision-making.

(26) The rules on Union market surveillance and on the control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to motor vehicles and their trailers, as well as to systems, components and separate technical units intended for such vehicles. Those rules do not prevent Member States from choosing