

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

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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

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the competent authorities that are to carry out those tasks. Market surveillance is a competence that may be shared between different national authorities, in order to take account of the national market surveillance systems in the Member States established under Regulation (EC) No 765/2008. Effective coordination and monitoring at Union and national levels should guarantee that approval authorities and market surveillance authorities enforce the new framework for type-approval and for market surveillance.

- (27) It is necessary to include rules on market surveillance in this Regulation in order to reinforce the rights and obligations of the national authorities, to ensure effective coordination of their market surveillance activities and to clarify the applicable procedures.
- (28) It is necessary for the market surveillance authorities and the approval authorities to be able to properly perform the tasks provided for by this Regulation. Member States should, in particular, equip them with the resources necessary in order to do so.
- (29) In order to increase transparency in the approval process and to facilitate the exchange of information and the independent verification by market surveillance authorities, approval authorities and the Commission, type-approval documentation should be provided in electronic format and be made publicly available, subject to exemptions concerning the protection of commercial secrets and the protection of personal data.
- (30) The obligations of national authorities concerning market surveillance provided in this Regulation are more specific than those laid down in Regulation (EC) No 765/2008. This is the result of the need to take account of the special characteristics of the framework for type-approval and the need to complement that framework with an effective market surveillance mechanism ensuring the robust verification of compliance of the automotive products covered by this Regulation. In order to ensure the functioning of the framework, it is essential that market surveillance authorities verify compliance of the automotive products irrespective of whether their type-approval was granted before or after the date of application of this Regulation.
- (31) It is essential for the proper functioning of market surveillance that the compliance of vehicles, systems, components and separate technical units on the market is verified on the basis of a robust risk-assessment. That verification of compliance, complemented by the establishment of a minimum number of checks on vehicles per year, would also contribute to the effective Union-wide implementation of the market surveillance obligations.
- (32) In view of the special characteristics of, and the potential risk linked to, emissions, an adequate share of the minimum number of checks should be allocated to emission-related tests. In order to ensure that vehicles comply fully, each single check should include verification that all the requirements for type-approval that apply to the vehicle being tested as regards emissions have been met.
- (33) It should be possible to use any tests carried out on any vehicle in any Member State for the purpose of taking corrective and restrictive measure in another Member State. The results of checks performed on vehicles within one Member State should be considered adequate for the purpose of invoking corrective and restrictive measures in

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another Member State. The physical transportation of the vehicles concerned should not, therefore, be necessary for the purpose of any checks which are carried out on behalf of another Member State.

- (34) It is of particular importance that national authorities and the Commission consider in-service conformity testing and inspections of vehicles to be part of their compliance verification procedures. The selection of the vehicles that are to be subject to that compliance verification should be based on an appropriate risk assessment which takes account of the seriousness of the possible non-compliance; the likelihood of its occurrence; and other possible indicators, such as the introduction of vehicles with new technology installed, any past history or reports of non-compliance, the results of remote sensing testing and the concerns expressed by recognised third parties.
- (35) In addition, in order to verify compliance with the relevant requirements, the Commission should organise and carry out compliance verification tests and inspections that are independent of those carried out by Member States under their national market surveillance obligations. Where such tests and inspections take place on registered vehicles in agreement with the holder of the vehicle registration certificate, it is important to take into account the fact that modified vehicles might be unsuited to such verification of compliance. It is also important to take into account the implications for the holder of the vehicle registration certificate, especially where the holder is a natural person, in the case of which the suitable way of selecting the vehicles is either by way of a public call or through the Member States' authorities. Where those tests and inspections establish non-compliance, or where it is found that a type-approval has been granted on the basis of incorrect data, the Commission should be entitled to initiate Union-wide remedial actions to restore the conformity of the vehicles concerned, and to investigate the reasons why the type-approval was incorrect. Appropriate funding should be ensured in the general budget of the Union to enable the execution of such compliance verification tests and inspections.
- (36) In order to support Member States in the task of detecting defeat devices, the Commission published, on 26 January 2017, Guidance on the evaluation of Auxiliary Emission Strategies and the presence of Defeat Devices with regard to the application of Regulation (EC) No 715/2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6). Consistent with that Guidance, the test activities of the Commission, of the type-approval authorities and of the technical services for the purpose of detecting defeat devices should remain non-predictable in character, and should also include modified testing conditions which entail variations in physical conditions and testing parameters.
- (37) In order to ensure a high level of vehicle functional safety, to ensure the protection of vehicle's occupants and other road users, and to ensure the protection of the environment and health, the technical requirements and environmental standards that apply to vehicles, systems, components and separate technical units should continue to be harmonised and adapted to reflect the technical and scientific progress.
- (38) The objective of this Regulation should not be affected by the fact that certain systems, components, separate technical units, parts and equipment can be fitted to or in a vehicle

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after that vehicle has been placed on the market, has been registered or has entered into service. Appropriate measures should therefore be taken to ensure that the systems, components, separate technical units or parts and equipment that can be fitted to or in vehicles and that can significantly impair the functioning of systems that are essential for environmental protection or functional safety are subject to controls by an approval authority before they are placed on the market, registered or entered into service.

- (39) Those measures should only apply to a limited number of parts or equipment. In the event of serious risk, the Commission should establish the list of such parts or equipment and the corresponding requirements as a matter of priority, after having consulted stakeholders. In establishing the list, the Commission should ensure in particular that replacement parts and equipment that are essential for emission controls and safety meet the performance specifications of the original parts and equipment. It should also consult stakeholders on the basis of a report, and should strive for a fair balance between the requirements of improving road safety and environmental protection, as well as a fair balance between the interests of consumers, manufacturers and distributors while preserving competition in the aftermarket.
- (40) The EU type-approval system has to enable each Member State to confirm that every type of vehicle and every type of system, component and separate technical unit intended for such type of vehicle has undergone the tests and inspections provided for in this Regulation to verify its compliance with the type-approval requirements of this Regulation and that its manufacturer has obtained a type-approval certificate for it. The EU type-approval system obliges manufacturers to produce their vehicles, systems, components and separate technical units in conformity with the approved type. A vehicle manufacturer has to certify this by issuing a certificate of conformity for every vehicle. Every vehicle which has a valid certificate of conformity should be permitted to be made available on the market and registered in the Union.
- (41) In order to simplify the exchange of information related to type-approval between the competent authorities and to make relevant information publically accessible after appropriate implementation periods, the use of searchable online databases should be compulsory. To preserve confidential data, it is important for all data exchange to be performed by means of secure data exchange protocols. Special attention should be paid to eliminating data misuse, including avoidance of creating multiple first time registrations when using certificates of conformity in electronic format.
- (42) Conformity of production is one of the cornerstones of the EU type-approval system, and therefore the arrangements set up by the manufacturer to ensure such conformity should be approved by the competent authority or by an appropriately qualified technical service designated for that purpose, and should be subject to regular verification by means of independent periodic audits. In addition, approval authorities should ensure the verification of the continued conformity of the automotive products concerned.
- (43) The continued validity of the type-approvals requires that the manufacturer inform the authority that has approved its type of vehicle of any changes to the characteristics of the type or to the safety and environmental performance requirements applicable

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to that type so that it can be verified that the type of vehicle continues to comply with all the applicable requirements. Furthermore, the conditions for amending type-approvals should be clarified to ensure the uniform application of the procedures and the enforcement of the type-approval requirements throughout the Union, in particular to ensure the strict application of the rules that distinguish between amended type-approvals and new type-approvals. To ensure that the latest requirements are implemented on all new vehicles at a certain point in time, it is important that regulatory acts listed in Annex II include not only a date for the application of new requirements to new type-approvals, but also a date as of which new requirements become mandatory for the making available on the market, registration or entry into service of vehicles, systems, components or separate technical units.

- (44) The assessment of reported serious risk to safety and of harm to public health and the environment should be conducted at national level, but coordination at Union level should be ensured where a reported risk or harm may extend beyond the territory of one Member State, with the objective of sharing resources and ensuring consistency regarding the corrective actions to be taken to mitigate the identified risk or harm.
- (45) In order to ensure that all vehicles, systems, components and separate technical units placed on the market offer a high level of safety and of environmental protection, the manufacturer or any other economic operator in the supply chain should take appropriate corrective measures, including recalling vehicles, where a vehicle, system, component or separate technical unit presents a serious risk to users or the environment as provided for in Regulation (EC) No 765/2008. Approval authorities should be empowered to assess and verify whether those corrective measures are adequate. The approval authorities of other Member States' should have the right to take corrective and restrictive measures where they consider that the manufacturer's corrective measures are not adequate.
- (46) Where corrective measures are applied, holders of registrations for affected vehicles should not bear the cost of the repairs to their vehicles, including in cases where repairs have been carried out at the registration holder's expense before the adoption of the corrective measure. This should not prevent consumers relying on remedies based on contract law, as applicable under Union or national law.
- (47) Appropriate flexibility should be provided by means of alternative approval schemes for manufacturers of vehicles produced in small series. They should be able to benefit from the advantages of the internal market, provided that their vehicles comply with the specific EU type-approval requirements for vehicles produced in small series. In certain limited cases, it is appropriate to allow for national small series type-approval. In order to prevent misuse, any simplified procedure for vehicles produced in small series should be restricted to cases involving very limited production in accordance with this Regulation. It is therefore necessary to precisely define the concept of vehicles produced in small series in terms of the number of vehicles produced, the requirements to be complied with and the conditions for placing those vehicles on the market. It is equally important to specify an alternative approval scheme for individual vehicles, in

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particular to provide sufficient flexibility for the approval of vehicles built in multiple stages.

- (48) The Union is a Contracting Party to the Agreement of the United Nations Economic Commission for Europe of 20 March 1958 concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement')⁽⁵⁾. The Union has accepted a significant number of Regulations annexed to the Revised 1958 Agreement, and therefore has the obligation to accept type-approvals granted in accordance with those Regulations as complying with the equivalent Union requirements. For the purpose of simplifying its framework for type-approval and aligning it with the international framework of the United Nations (UN), in Regulation (EC) No 661/2009 of the European Parliament and of the Council⁽⁶⁾, the Union repealed its specific type-approval Directives and replaced them with the obligatory application of the relevant UN Regulations. To reduce the administrative burden of the type-approval process, where appropriate, manufacturers of vehicles, systems, components and separate technical units should be allowed to seek type-approval directly in accordance with this Regulation by obtaining approval under the relevant UN Regulations referred to in the Annexes to this Regulation.
- (49) Consequently, the UN Regulations and the amendments thereto which the Union has voted in favour of or that the Union applies in accordance with Decision 97/836/EC should be incorporated within the EU type-approval legislation. Accordingly, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend the Annexes to this Regulation to ensure that the references to the UN Regulations and their respective amendments in the list of the relevant regulatory acts are kept up-to-date.
- (50) Unrestricted access to vehicle repair and maintenance information, via a standardised format that can be used to retrieve the technical information, and effective competition in the market for services providing such information, are necessary to improve the functioning of the internal market, in particular as regards the free movement of goods, the freedom of establishment and the freedom to provide services. The requirements for the provision of repair and maintenance information have so far been laid down in Regulations (EC) No 715/2007⁽⁷⁾ and (EC) No 595/2009⁽⁸⁾ of the European Parliament and of the Council. Those requirements should be consolidated in this Regulation and Regulations (EC) No 715/2007 and (EC) No 595/2009 should be amended accordingly.
- (51) Technical progress introducing new methods or techniques for vehicle diagnostics and repair, such as remote access to vehicle information and software, should not weaken the objective of this Regulation with respect to access to vehicle repair and maintenance information for independent operators.
- (52) In order to ensure effective competition in the market for vehicle repair and maintenance information services, and in order to clarify that the information concerned also covers information which needs to be provided to independent operators other than repairers, so as to ensure that the independent vehicle repair and maintenance market as a whole

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can compete with authorised dealers, regardless of whether the vehicle manufacturer gives such information to authorised dealers and repairers or uses such information for the repair and maintenance purposes itself, it is necessary to set out the details of the information to be provided for the purposes of access to vehicle repair and maintenance information.

- (53) For the inspection of vehicles, and in particular for their safety- and environment-related components, it is considered to be necessary for testing centres and relevant competent authorities to have access to the technical information of each individual vehicle, as set out in Directive 2014/45/EU of the European Parliament and of the Council⁽⁹⁾. In order to facilitate compliance with the requirements laid down in that Directive, the independent operators should have access to the relevant technical information needed for the preparation of vehicles for road worthiness tests.
- (54) Since there is currently no common structured process for the exchange of vehicle component data between vehicle manufacturers and independent operators, it is appropriate to develop principles for such exchanges of data. A future common structured process on the standardised format of the exchanges of data should be formally developed by the European Committee for Standardisation (CEN), although the mandate given to CEN does not predetermine the level of detail that standard will provide. The CEN's work should, in particular, reflect the interests and needs of vehicle manufacturers and independent operators alike and should also investigate solutions such as open data formats described by well-defined meta-data to accommodate existing information technology infrastructures.
- (55) In order to ensure the effectiveness of this Regulation, the power to adopt acts in accordance with Article 290 of the TFEU should be delegated to the Commission in respect of type-approval requirements concerning the environmental and safety performance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁽¹⁰⁾. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (56) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽¹¹⁾.
- (57) Member States should lay down rules on penalties for the infringements of this Regulation, and should ensure that those rules are implemented. Those penalties should be effective, proportionate and dissuasive. In particular, they should reflect, the risk to safety, health or the environment that the number of non-compliant vehicles, systems, components or separate technical units made available on the market could pose.

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- Member States should report the imposed penalties to the Commission annually, to monitor the coherence of the implementation of those rules.
- (58) When performing compliance verification testing, technical services should be able to choose the parameters of the tests freely and in a non-predictable manner from within the range provided for in the relevant regulatory acts. This should help them verify that the vehicles tested are compliant across the whole range of parameters, including the parameters that correspond to the worst case for the test.
- (59) In order to ensure that the vehicles, systems, components and separate technical units comply with this Regulation in all cases, they should be deemed not to comply with the relevant requirements where test results cannot be empirically verified by the relevant authority even though all testing parameters have been replicated or taken into account. It is necessary to impose penalties on economic operators and technical services who falsify test results or submit false declarations or incorrect data for type-approval.
- (60) In the interests of clarity, rationality and simplification, Directive 2007/46/EC should be repealed and replaced by this Regulation. The adoption of this Regulation ensures that provisions are directly applicable and that they can be updated in a timely and more efficient manner to take better account of technical progress and regulatory developments in the context of the Revised 1958 Agreement.
- (61) In order to support corrective and restrictive measures at Union level, the Commission should have the power to impose harmonised administrative fines upon the economic operators found to have infringed upon this Regulation regardless of where a vehicle, system, component or separate technical unit was originally type-approved. The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to supplement this Regulation by laying down the procedure for, and methods for calculation and collection of, those administrative fines, on the basis of the principles laid down in this Regulation.
- (62) Whenever the measures provided for in this Regulation entail the processing of personal data, they should be carried out in accordance with Regulations (EU) 2016/679⁽¹²⁾ and (EC) No 45/2001⁽¹³⁾ of the European Parliament and of the Council as well as the national implementing measures thereto. It is important that manufacturers implement all measures necessary to comply with the rules on processing and transmission of personal data that are generated while the vehicle is used.
- (63) In order to enable Member States and national authorities as well as economic operators to prepare for the application of the new rules introduced by this Regulation, a date of application falling after the date of the entry into force should be set.
- (64) Since the objective of this Regulation, namely laying down administrative provisions and technical requirements for the type-approval of new vehicles of categories M, N and O, and for the type-approval of systems, components and separate technical units intended for such vehicles, as well as for the market surveillance of such vehicles, systems, components and separate technical units, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures in accordance with the principle of

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subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

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- (1) [OJ C 303, 19.8.2016, p. 86.](#)
- (2) Position of the European Parliament of 19 April 2018 (not yet published in the Official Journal) and decision of the Council of 22 May 2018.
- (3) Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) ([OJ L 263, 9.10.2007, p. 1](#)).
- (4) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 ([OJ L 218, 13.8.2008, p. 30](#)).
- (5) Council Decision 97/836/EC of 27 November 1997 with a view to accession by the European Community to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement') ([OJ L 346, 17.12.1997, p. 78](#)).
- (6) Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor ([OJ L 200, 31.7.2009, p. 1](#)).
- (7) Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information ([OJ L 171, 29.6.2007, p. 1](#)).
- (8) Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC ([OJ L 188, 18.7.2009, p. 1](#)).
- (9) Directive 2014/45/EU of the European Parliament and of the Council of 3 April 2014 on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC ([OJ L 127, 29.4.2014, p. 51](#)).
- (10) [OJ L 123, 12.5.2016, p. 1.](#)
- (11) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13](#)).
- (12) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) ([OJ L 119, 4.5.2016, p. 1](#)).
- (13) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data ([OJ L 8, 12.1.2001, p. 1](#)).

Changes to legislation:

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