ANNEX IV

CONFORMITY OF PRODUCTION PROCEDURES

1. Objectives

1.1. The conformity of production procedure aims to ensure that each vehicle, system, component and technical separate unit, part or equipment produced is in conformity with the approved type.

1.2. The conformity of production procedure shall always include the assessment of quality-assurance management systems, referred to in point 2 as the 'initial assessment', and the verification of the type-approval subject and product-related controls, referred to in point 3 as 'product conformity arrangements'.

2. Initial assessment

2.1. Before granting type-approval, the approval authority shall verify that the manufacturer has established satisfactory arrangements and procedures for ensuring that vehicles, systems, components, separate technical units or parts and equipment are produced in conformity with the approved type.

2.2. Guidance for conducting those assessments may be found in standard EN ISO 19011:2011 — Guidelines for auditing management systems.

2.3. Compliance with the requirements of point 2.1 shall be verified to the satisfaction of the approval authority, as follows:

The approval authority shall be satisfied with the initial assessment and the product conformity arrangements referred to in point 3, taking into account one of the arrangements referred to in points 2.3.1 to 2.3.3, or a combination of those arrangements in full or in part as appropriate.

2.3.1. The initial assessment and verification of product conformity arrangements shall be carried out by the approval authority or a body designated for that purpose by the approval authority.

2.3.1.1. When considering the extent of the initial assessment to be carried out, the approval authority may take into account the following information:

(a) whether the manufacturer has a certification similar to the one referred to in point 2.3.3, but which has not been qualified or recognised under that point;

(b) in the case of a type-approval of a system, component or separate technical unit, quality system assessments that have been performed by vehicle manufacturer(s) in the premises of the manufacturer of the system, component or separate technical unit, in accordance with one or more of the industry sector specifications satisfying the requirements in the standard EN ISO 9001:2015 or ISO/TS16949:2009;

(c) whether in one of the Member States one or more of the manufacturer's type-approvals recently have been withdrawn, due to unsatisfactory control of conformity of production. In that case, the initial assessment by the approval authority shall not be limited to accepting the manufacturer's quality system certification, but shall include a verification whether all necessary improvements for ensuring effective control have been implemented, so that vehicles, components, systems or separate technical units are produced in conformity with the approved type.

2.3.2. The initial assessment and verification of product conformity arrangements may be carried out by the approval authority of another Member State or by the body designated for that purpose by the approval authority.

2.3.2.1. The approval authority of that other Member State shall in that case prepare a statement of compliance, which outlines the areas and production facilities that that approval authority has covered as relevant to the product(s) to be type-approved and to the regulatory acts in accordance with which these products are to be type-approved.

2.3.2.2. Upon receiving a request for a statement of compliance from the approval authority of a Member State granting type-approval, the approval authority of another Member State shall immediately send that statement of compliance or inform that approval authority that is unable to provide such a statement.

2.3.2.3. The statement of compliance shall include at least the following:

(a)	Group or company	(e.g. XYZ Automotive)
(b)	Particular organisation	(e.g. regional Division)
(c)	Plants/Sites	(e.g. Engine Plant 1 (in country A) — Vehicle Plant 2 (in country B))
(d)	Vehicle/Component range	(e.g. All Category M_1 models)
(e)	Areas assessed	(e.g. Engine assembly, body pressing and assembly, vehicle assembly)
(f)	Documents examined	(e.g. Company and site quality manual and procedures)
(g)	Date of the assessment	(e.g. Audit conducted from dd/mm/yyyy to dd/mm/yyyy)
(h)	Planned monitoring visit	(e.g. mm/yyyy)

2.3.3. An approval authority may also accept the manufacturer's certification to standards EN ISO 9001:2015 or ISO/TS16949:2009 (the scope of that certification shall in that case cover the product(s) to be approved), or an equivalent certification standard as satisfying the initial assessment requirements of point 2.3., provided that conformity of production is indeed covered by the quality management system and that the manufacturer's type-approval has not been withdrawn as referred to in point 2.3.1.1. (c). The manufacturer shall provide details of the certification and inform the approval authority of any revisions to its validity or scope.

2.4. For the purpose of vehicle type-approval, the initial assessments carried out for the granting of type-approvals for systems, components and separate technical units of the vehicle need not be repeated, but shall be completed by an assessment of the locations and activities relating to the assembly of the whole vehicle that have not been covered by the initial assessments.

3. Product conformity arrangements

3.1. Every vehicle, system, component or separate technical unit, part or item of equipment approved pursuant to a UN Regulation annexed to the Revised 1958 Agreement and to this Regulation shall be so manufactured as to conform to the type approved by meeting the requirements of this Annex, the said UN Regulation and this Regulation.

3.2. Before granting a type-approval pursuant to this Regulation and to a UN Regulation annexed to the Revised 1958 Agreement, the approval authority shall verify the existence of adequate product conformity arrangements and documented control plans, to be agreed with the manufacturer for each approval, to carry out at specified intervals the tests or associated checks that are necessary to verify continued conformity with the approved type, including, where applicable, tests specified in this Regulation and the said UN Regulation.

3.3. The holder of the type-approval shall, in particular:

3.3.1. ensure the existence and application of procedures for effective control of the conformity of vehicles, systems, components, separate technical units, parts or equipment to the approved type;

3.3.2. have access to the testing or other appropriate equipment necessary for checking the conformity to each approved type;

3.3.3. ensure that the data resulting from tests or checks are recorded and that annexed documents remain available for a period of up to 10 years to be determined in agreement with the approval authority;

3.3.4. analyse the results of each type of test or check, in order to verify and ensure the stability of the product characteristics, making allowance for variation of an industrial production;

3.3.5. ensure that for each type of product, at least the checks prescribed in this Regulation and the tests prescribed in the relevant regulatory acts listed in Annex II are carried out;

3.3.6. ensure that any set of samples or test pieces that gives evidence of non-conformity in the type of test in question, gives rise to a further sampling and testing. All the necessary steps shall be taken to restore the production process to ensure conformity with the approved type.

3.4. In the case of step-by-step, mixed or multi-stage type-approvals, the approval authority that is granting a whole-vehicle type-approval may request from any approval authority that has granted type-approval of any relevant system, component or separate technical unit specific details regarding compliance with the conformity of production requirements set out in this Annex.

3.5. The approval authority that is granting a whole-vehicle type-approval and is not satisfied with the reported information referred to in point 3.4., and that has communicated this in writing to the relevant manufacturer and to the approval authority granting the type-approval for the system, component or separate technical unit, shall request the performance of additional conformity of production audits or checks, which shall be performed at the site of the manufacturer(s) of those systems, components or separate technical units. The results of this additional conformity of production audits or checks shall immediately be made available to that approval authority.

3.6. Where points 3.4. and 3.5. apply and the approval authority granting the whole-vehicle type-approval has not been satisfied with the additional audit or check results, the

manufacturer shall ensure that conformity of production is restored as soon as possible to the satisfaction of that approval authority and of the approval authority granting type-approval of the system, component or separate technical unit.

4. Continued verification arrangements

4.1. The approval authority that has granted type-approval may at any time verify the conformity control methods applied in each production facility by means of periodic audits. The manufacturer shall for that purpose allow access to that authority to the manufacturing, inspection, testing, storage and distribution sites and shall provide all necessary information with regard to the quality management system documentation and records.

4.1.1. The normal arrangements for such periodic audits shall be to monitor the continued effectiveness of the procedures laid down in points 2 and 3 (initial assessment and product conformity arrangements).

4.1.1.1. Surveillance activities carried out by the technical services (qualified or recognised as required in point 2.3.3) shall be accepted as satisfying the requirement of point 4.1.1 with regard to the procedures established at initial assessment.

4.1.1.2. The normal frequency of verifications by the approval authority (other than those referred to in point 4.1.1.1) shall be such as to ensure that the relevant controls applied in accordance with points 2 and 3 are reviewed at intervals based on a risk assessment methodology that complies with the international standard ISO 31000:2018 – Risk Management – Principles and Guidelines, and such verification shall in any case be conducted at least once every three years. This methodology shall in particular take into account any non-conformity raised by other Member States in the context of Article 54(1).

4.2. At every review, records of tests or checks and records of production, in particular records of those tests or checks documented as required in point 2.2, shall be made available to the inspector.

4.3. The inspector may select samples at random manner to be tested in the manufacturer's laboratory or in the facilities of the technical service. In such a case only physical test shall be carried out. The minimum number of samples may be determined on the basis of the results of the manufacturer's own verification.

4.4. The inspector who is of the opinion that the level of control is unsatisfactory, or who deems it necessary to verify the validity of the tests carried out in accordance with point 4.2, shall select samples to be sent to a technical service to perform physical tests in accordance with the requirements on conformity of production, set out in the regulatory acts listed in Annex II.

4.5. Where unsatisfactory results are found during an inspection or a monitoring review, the approval authority shall take all necessary steps to ensure that the manufacturer restores the conformity of production as rapidly as possible.

4.6. In cases where compliance with UN Regulations is required by this Regulation, the manufacturer may choose to apply this Annex as an equivalent alternative to the conformity of production requirements in the respective UN Regulations. However, if points 4.4. or 4.5. apply, all separate conformity of production requirements in the UN Regulations have to be complied with to the satisfaction of the approval authority until it decides that conformity of production has been restored.

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2018/858 of the European Parliament and of the Council, ANNEX IV.