

**ANNEX to Commission Delegated Regulation (EU) .../... amending Regulation
(EU) No 748/2012 as regards updating the references to the environmental protection
requirements and correcting that Regulation**

ANNEX

Annex I (Part 21) to Regulation (EU) No 748/2012 is amended as follows:

- (1) the table of contents ('Contents') is amended as follows:
 - (a) the title of point 21.A.91 is replaced by the following:
'21.A.91 Classification of changes to a type certificate';
 - (b) the title of point 21.A.433 is replaced by the following:
'21.A.433 Requirements for the approval of a repair design';
 - (c) the title of point 21.B.85 is replaced by the following:
'21.B.85 Applicable environmental protection requirements for a type certificate or restricted type certificate';
 - (d) the title of point 21.B.105 is replaced by the following:
'21.B. 105 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a major change to a type certificate';
 - (e) the title of point 21.B.109 is replaced by the following:
'21.B.109 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a supplemental type certificate';
 - (f) the title of point 21.B.450 is replaced by the following:
'21.B.450 Amendments to the type-certification basis for a repair design approval';
- (2) in point 21.A.15(b), point (6) is replaced by the following:
 - '6. a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or environmental protection requirements and the potential impact of that non-compliance on the product or UAS safety or environmental compatibility or on the safety of the CMU. The proposed assessment shall take into account at least the elements set out in points (1) to (4) of point 21.B.100(a). Based on that assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data;';

- (3) point 21.A.91 is replaced by the following:

‘21.A.91 Classification of changes to a type certificate

Changes to a type certificate shall be classified as ‘minor’ and ‘major’. A ‘minor change’ has no appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, certified noise or emissions levels, operational suitability data, or other characteristics affecting the airworthiness or the environmental compatibility of the product or of the UAS, or no appreciable effect on the reliability, operational characteristics, or other characteristics affecting the airworthiness of the CMU. Without prejudice to point 21.A.19, all other changes shall be considered ‘major changes’ under this Subpart. Major and minor changes shall be approved in accordance with points 21.A.95 or 21.A.97, as appropriate, and shall be adequately identified.’;

- (4) in point 21.A.93(b)(3), point (iii) is replaced by the following:

‘(iii) a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the applicable type-certification basis, operational suitability data certification basis or environmental protection requirements and the potential impact of that non-compliance on the product or UAS safety or environmental compatibility or on the safety of the CMU; the proposed assessment shall take into account at least the elements set out in points (1) to (4) of point 21.B.100(a). Based on that assessment, the application shall include a proposal for the Agency’s involvement in the verification of the compliance demonstration activities and data; and’;

- (5) in point 21.A.95(b), point (3) is replaced by the following:

‘3. when compliance with the type-certification basis and the environmental protection requirements that apply in accordance with point (1) has been declared and the justifications of compliance have been recorded in the compliance documents; and’;

- (6) point 21.A.147 is replaced by the following:

‘21.A.147 Changes in the production management system

After the issue of a production organisation approval certificate, each change in the production management system that is significant for the demonstration of conformity or the airworthiness and environmental compatibility characteristics of the product, part, appliance, UAS, CMU or CMU component shall be approved by the competent authority before being implemented. The production organisation shall submit an application for approval to the competent authority demonstrating that it will continue to comply with the provisions of this Annex.’;

- (7) in point 21.A.165(c), the introductory phrase of point (3) is replaced by the following:

‘3. additionally, in the case of environmental protection, determine that:’;

- (8) in point 21.A.243, point (d) is replaced by the following:

‘(d) The design organisation shall establish and maintain a statement of the qualifications and experience of the management staff and of other persons in the organisation that are responsible for making decisions that affect airworthiness, operational suitability data and environmental compatibility. It shall submit that statement to the competent authority.’;

(9) in point 21.A.245(e), point (2) is replaced by the following:

‘2. there is full and efficient coordination between the departments and within the departments in respect of airworthiness, operational suitability data and environmental compatibility.’;

(10) point 21.A.247 is replaced by the following:

‘21.A.247 Changes in the design management system

After the issue of a design organisation approval, each change to the design management system that is significant for the demonstration of compliance or for the airworthiness, operational suitability data and environmental compatibility of the product, part, appliance, UAS, CMU or CMU component shall be approved by the Agency before being implemented. The design organisation shall submit to the Agency an application for approval demonstrating, on the basis of the proposed changes to the handbook, that it will continue to comply with the provisions of this Annex.’;

(11) point 21.A.251 is replaced by the following:

‘21.A.251 Terms of approval

The terms of approval shall identify the types of design work, the categories of products, parts, appliances, UAS, CMUs or CMU components for which the design organisation holds a design organisation approval, and the functions and duties that the organisation is approved to perform with regard to the airworthiness, operational suitability data and environmental compatibility characteristics of the products, UAS or CMUs. For design organisation approvals covering type-certification or European Technical Standard Order (ETSO) authorisation for auxiliary power units (APUs), the terms of approval shall additionally contain the list of products, CMUs or APUs. Those terms shall be issued as part of a design organisation approval.’;

(12) in point 21.A.432C, point (b) is amended as follows:

(a) points (2) and (3) are replaced by the following:

- ‘2. the identification of all areas of the type design and the approved manuals that are changed or affected by the repair design;
3. the identification of any reinvestigations necessary to demonstrate compliance of the repair design and areas affected by the repair design with the type-certification basis and the applicable environmental protection requirements incorporated by reference in, as applicable, either the type certificate, the supplemental type certificate or the APU ETSO authorisation;’;

(b) point (6) is replaced by the following:

- ‘6. a proposal for the assessment of the meaningful groups of compliance demonstration activities and data, addressing the likelihood of an unidentified non-compliance with the type-certification basis or the applicable environmental protection requirements and the potential impact of that non-compliance on the product, UAS or CMU safety or environmental compatibility. The proposed assessment shall take into account at least the elements set out in point 21.B.100(a), points 1 to 4. Based on that assessment, the application shall include a proposal for the Agency’s

involvement in the verification of the compliance demonstration activities and data; and’;

(13) point 21.A.433 is amended as follows:

(a) the title is replaced by the following:

‘21.A.433 Requirements for the approval of a repair design’;

(b) in point (a), points (1) and (2) are replaced by the following:

- ‘1. when it has been demonstrated, following the certification programme referred to in point 21.A.432C(b), that the repair design complies with the type-certification basis and the environmental protection requirements incorporated by reference in, as applicable, either the type certificate, the supplemental type certificate or the APU ETSO authorisation, as well as with any amendments established and notified by the Agency in accordance with point 21.B.450;
2. when compliance with the type-certification basis and the environmental protection requirements that apply in accordance with point (a)(1) has been declared and the justifications of compliance have been recorded in the compliance documents;’;

(14) in point 21.A.701(a), point (14) is replaced by the following:

‘14. flying aircraft meeting the applicable airworthiness requirements before conformity to the applicable environmental protection requirements has been demonstrated;’;

(15) point 21.B.70 is replaced by the following:

‘21.B.70 Certification specifications

The Agency, in accordance with Article 76(3) of Regulation (EU) 2018/1139, shall issue certification specifications and other detailed specifications, including certification specifications for airworthiness and operational suitability data, which competent authorities, organisations and personnel may use to demonstrate compliance of products, parts, appliances, UAS, CMUs and CMU components with the relevant essential requirements set out in Annexes II, IV, V and IX to that Regulation. Such specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which certificates shall be issued, amended or supplemented.’;

(16) in point 21.B.85, the title and point (a) are replaced by the following:

‘21.B.85 Applicable environmental protection requirements for a type certificate or restricted type certificate

(a) For a type certificate or restricted type certificate for an aircraft or for a type certificate for an engine, the Agency shall designate and notify to the applicant the applicable environmental protection requirements from the essential requirements referred to in the first subparagraph of Article 9(2) of Regulation (EU) 2018/1139.’;

(17) in point 21.B.100(a), the introductory paragraph is replaced by the following:

- ‘(a) The Agency shall determine its involvement in the verification of the compliance demonstration activities and data related to the application for a type certificate, restricted type certificate, major change approval, supplemental type certificate, major repair design approval or ETSO authorisation for APUs. It shall do so on the basis of an assessment of meaningful groups of compliance demonstration activities and data of the certification programme. That assessment shall address:
- the likelihood of an unidentified non-compliance with the type-certification basis, operational suitability data certification basis or applicable environmental protection requirements; and
 - the potential impact of that non-compliance on product, UAS and CMU safety or environmental compatibility,
- and consider at least the following elements:’;

(18) point 21.B.105 is replaced by the following:

‘21.B.105 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a major change to a type certificate

The Agency shall establish the applicable type-certification basis, the applicable environmental protection requirements and, in the case of a change affecting the operational suitability data, the operational suitability data certification basis established in accordance with point 21.A.101 and notify them to the applicant for a major change to a type certificate.’;

(19) point 21.B.109 is replaced by the following:

‘21.B.109 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a supplemental type certificate

The Agency shall establish the applicable type-certification basis, the applicable environmental protection requirements and, in the case of a change affecting the operational suitability data, the operational suitability data certification basis established in accordance with point 21.A.101 and notify them to the applicant for a supplemental type certificate.’;

(20) in point 21.B.450, the title is replaced by the following:

‘21.B.450 Amendments to the type-certification basis for a repair design approval’;

(21) point 21.B.453 is amended as follows:

(a) in point (a), point (3) is replaced by the following:

- ‘3. the Agency, through its verification of the demonstration of compliance in accordance with the level of involvement established pursuant to point 21.B.100(a), has not found any non-compliance with the type-certification basis and the applicable environmental protection requirements; and’;

(b) point (b) is replaced by the following:

- ‘(b) The Agency shall issue an approval of a minor repair design, provided that the applicant has complied with points (2) and (4) of point (a) and provided

that the Agency, through its verification of the demonstration of compliance in accordance with the level of involvement pursuant to point 21.B.100(b), has not found any non-compliance with the type-certification basis and the applicable environmental protection requirements.’;

(22) Appendix VII is replaced by the following:

Appendix VII

For use by State of registry		1. State of registry		3. Document No:	
2. NOISE CERTIFICATE					
4. Registration marks: 		5. Manufacturer and manufacturer's designation of the aircraft: 		6. Aircraft serial No: 	
7. Manufacturer and manufacturer's designation of the engine(s): 			8. Manufacturer and manufacturer's designation of the propeller(s): ⁽¹⁾ 		
9. Maximum take-off mass (kg): 		10. Maximum landing mass (kg): ⁽¹⁾ 		11. Noise certification standard: 	
12. Additional modifications incorporated for the purpose of compliance with the applicable noise certification standards: 					
13. Lateral/full-power noise level: ⁽¹⁾ 	14. Approach noise level: ⁽¹⁾ 	15. Flyover noise level: ⁽¹⁾ 	16. Overflight noise level: ⁽¹⁾ 	17. Take-off noise level: ⁽¹⁾ 	
Remarks: 					
18. This noise certificate is issued pursuant to Annex 16, Volume I to the Convention on International Civil Aviation dated 7 December 1944 and Article 14(1) of Regulation (EU) 2018/1139 in respect of the above-mentioned aircraft, which is considered to comply with the indicated noise standard when maintained and operated in accordance with the relevant requirements and operating limitations.					
19. Date of issue				20. Signature	
.....					

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(1) These boxes may be omitted depending on the noise certification standard.