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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, ... C

Draft

COMMISSION REGULATION (EU) No .../...

of [...]

amending Commission Regulation (EC) No 1702/2003 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations

(Text with EEA relevance)

Draft

COMMISSION REGULATION (EU) No .../...

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amending Commission Regulation (EC) No 1702/2003 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, in particular Article 80(2) thereof,

Having regard to Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC¹ (hereafter referred to as the 'Basic Regulation'), and in particular Article 5(5) thereof,

Whereas:

- (1) With the replacement of Regulation (EC) No 1592/2002 by Regulation (EC) No 216/2008, Article 5 dealing with airworthiness was extended to include the elements of operational suitability evaluation into the implementing rules for type-certification.
- (2) The European Aviation Safety Agency (hereafter referred to as the 'Agency') has found it necessary to propose amendments to Commission Regulation (EC) No 1702/2003 in order to allow the Agency to approve operational suitability data as part of the type-certification process.
- (3) The measures provided for in this Regulation are based on the Opinion issued by the Agency² in accordance with Articles 17(2)(b) and 19(1) of Regulation (EC) No 216/2008.
- (4) The measures provided for in this Regulation are in accordance with the Opinion³ of the European Aviation Safety Agency Committee established by Article 65(3) of Regulation (EC) No 216/2008.
- (5) Commission Regulation (EC) No 1702/2003 should therefore be amended accordingly.

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1702/2003 is amended as follows:

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OJ L 79, 19.03.2008, p. 1.

² Opinion 06/2008.

³ (To be issued).

- 1. In Article 1(2) the following point (i) is added:
 - '(i) 'European Union operator' means an operator having its principal place of business in a Member State.'
- 2. The following Article 2f is added:

'Article 2f

Operational Suitability Data

- 1. The holder of an aircraft type-certificate issued before the entry into force of this Regulation intending to deliver a new aircraft to a European Union operator on or after the entry into force of this Regulation shall obtain approval in accordance with Part 21A.21(e) except for the minimum syllabus of maintenance certifying staff type rating training and except for aircraft validation source data to support the objective qualification of simulator(s). The approval shall be obtained within two years after the entry into force of this Regulation or before the aircraft is operated by a European Union operator, whichever is the latest. The operational suitability data can be limited to the model which is delivered.
- 2. The applicant for an aircraft type-certificate for which the application was filed before the entry into force of this Regulation and for which a type-certificate is not issued before the entry into force of this Regulation shall obtain approval in accordance with Part 21A.21(e) except for the minimum syllabus of maintenance certifying staff type rating training and for aircraft validation source data to support the objective qualification of simulator(s). The approval shall be obtained within two years after the entry into force of this Regulation or before the aircraft is operated by a European Union operator, whichever is the latest. Compliance findings made by the authorities in Operational Evaluation Board processes conducted under the responsibility of the Joint Aviation Authorities (JAA) or EASA before the entry into force of this Regulation shall be accepted by the EASA without further verification.
- 3. Operational Evaluation Board Reports issued in accordance with JAA procedures or by the Agency before the entry into force of this Regulation shall be deemed to constitute the Operational Suitability Data approved in accordance with Part 21A.21(e) and shall be deemed to have been included in the relevant type-certificate. The data shall be distinguished in mandatory data or recommended data in accordance with the applicable Certification Specifications issued by the Agency.
- 4. Holders of a type-certificate including operational suitability data shall obtain approval of an extension of the scope of their design organisation approval or alternative procedures to design organisation approval, as applicable, to include operational suitability aspects within two years after the entry into force of this Regulation.'
- 3. The Annex (Part-21) to Commission Regulation (EC) 1702/2003 is amended as set out in the Annex to this Regulation.

Article 2

Entry into force

- 1. This Regulation shall enter into force the 20th day following its publication in the *Official Journal of the European Union*.
- 2. By way of derogation from point 1, the amendments to Subparts D and E of Part-21 will not be mandatory for applicants for the approval of a change to a type-certificate as well as

applicants for a Supplemental Type-Certificate until three years after the entry into force of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, XXXX.

For the Commission
[...]
The President

ANNEX

The Annex (Part-21) to Commission Regulation (EC) 1702/2003 is amended as follows:

- 1. in point 21A.14(b), point 4 is replaced by the following:
 - '4. an engine or a propeller type-certificated under the applicable Certification Specifications for powered sailplanes; or'
- 2. in point 21A.15, the following point (d) is added:
 - '(d) An application for a type-certificate or restricted type-certificate for an aircraft shall include, or be supplemented after the initial application to include the application for approval of operational suitability data, consisting of, as applicable:
 - 1. the minimum syllabus of pilot type rating training, including determination of type rating;
 - 2. the definition of scope of the aircraft validation source data to support the objective qualification of simulator(s) associated to the pilot type rating training, or provisional data to support their interim qualification;
 - 3. the minimum syllabus of maintenance certifying staff type rating training, including determination of type rating;
 - 4. determination of type or variant for cabin crew and type specific data for cabin crew training;
 - 5. the master minimum equipment list; and
 - 6 other type-related operational suitability elements.'
- 3. point 21A.16 is replaced by the following:

'21A.16A Certification Specifications

The Agency shall issue in accordance with Article 19 of the Basic Regulation Certification Specifications, including Certification Specifications for operational suitability data, as standard means to demonstrate compliance of products, parts and appliances with the relevant essential requirements of Annex I, III and IV to the Basic Regulation. Such specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which certificates will be issued, amended or supplemented.'

4. point 21A.16B is replaced by the following:

'21A.16B Special conditions

- (a) The Agency shall prescribe special detailed technical specifications, named special conditions, for a product if the related Certification Specifications do not contain adequate or appropriate safety standards for the product, because:
 - 1. The product has novel or unusual design features relative to the design practices on which the applicable Certification Specifications are based; or
 - 2. The intended use of the product is unconventional; or
 - 3. Experience from other similar products in service or products having similar design features, has shown that unsafe conditions may develop.

- (b) The special conditions contain such safety standards as the Agency finds necessary to establish a level of safety equivalent to that established in the applicable Certification Specifications.'
- 5. point 21A.17 is replaced by the following:

'21A.17A Type-certification basis

- (a) The type-certification basis to be notified for the issuance of a type-certificate or a restricted type-certificate shall consist of:
 - 1. The applicable Certification Specifications established by the Agency that are effective on the date of application for that certificate unless:
 - (i) Otherwise specified by the Agency; or
 - (ii) Compliance with later effective amendments is elected by the applicant or required under paragraphs (c) and (d).
 - 2. Any special condition prescribed in accordance with 21A.16B(a).
- (b) An application for type-certification of large aeroplanes and large rotorcraft shall be effective for five years and an application for any other type-certificate shall be effective for three years, unless an applicant shows at the time of application that its product requires a longer period of time for design, development, and testing, and the Agency approves a longer period.
- (c) In the case where a type-certificate has not been issued, or it is clear that a type-certificate will not be issued, within the time limit established under paragraph (b), the applicant may:
 - 1. File a new application for a type-certificate and comply with all the provisions of paragraph (a) applicable to an original application; or
 - 2. File for an extension of the original application and comply with the applicable Certification Specifications that were effective on a date, to be selected by the applicant, not earlier than the date which precedes the date of issue of the type-certificate by the time limit established under paragraph (b) for the original application.
- (d) If an applicant elects to comply with an amendment to the Certification Specifications that is effective after the filing of the application for a type-certificate, the applicant shall also comply with any other amendment that the Agency finds is directly related.'
- 6. the following point 21A.17B is added:

'21A.17B Operational suitability data certification basis

- (a) The Agency shall notify to the applicant the operational suitability data certification basis. It shall consist of:
 - 1. The applicable Certification Specifications for operational suitability data issued in accordance with 21A.16A that are effective on the date of application or application supplement, unless:
 - (i) The Agency accepts other means to demonstrate compliance with the relevant essential requirements of Annexes I, III and IV to the Basic Regulation; or

- (ii) Compliance with later effective amendments is elected by the applicant.
- 2. Any special condition prescribed in accordance with 21A.16B(a).
- (b) If an applicant elects to comply with an amendment to the Certification Specifications that are effective after the filing of the application for a type-certificate, the applicant shall also comply with any other amendment that the Agency finds is directly related.'
- 7. point 21A.20 is replaced by the following:

Compliance with the type-certification basis, operational suitability data certification basis and environmental protection requirements

- (a) The applicant for a type-certificate or a restricted type-certificate shall show compliance with the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements and shall provide to the Agency the means by which such compliance has been shown.
- (b) The applicant shall declare that it has shown compliance with all applicable typecertification basis, the applicable operational suitability data certification basis and environmental protection requirements.
- (c) Where the applicant holds an appropriate design organisation approval, the declaration of paragraph (b) shall be made according to the provisions of Subpart J.'
- 8. in point 21A.21, points (b) and (c)1. are replaced and points (e) and (f) are added as follows:
 - '(b) submitting the declaration referred to in 21A.20(b);
 - (c) it is shown that:
 - 1. The product to be certificated meets the applicable type-certification basis and environmental protection requirements designated in accordance with 21A.17A and 21A.18;
 - (e) In the case of an aircraft type-certificate, it is shown that the operational suitability data meets the applicable operational suitability data certification basis designated in accordance with 21A.17B.
 - (f) By derogation from point (e), an aircraft type-certificate may be issued before compliance with the applicable operational suitability data certification basis has been shown. In this case, the validity of the type-certificate shall be conditioned to the applicant demonstrating compliance with the operational suitability data certification basis before that data must be used by a training organisation or a European Union operator. By derogation from 21A.20, the declaration referred to in point (b) shall state the date by which compliance will be shown.
- 9. point 21A.23 is replaced by the following:

'21A.23 Issue of a restricted type-certificate

- (a) For an aircraft that does not meet the provisions of 21A.21(c), the applicant shall be entitled to have a restricted type-certificate issued by the Agency after:
 - 1. complying with the appropriate type-certification basis established by the Agency ensuring adequate safety with regard to the intended use of the aircraft, and with the applicable environmental protection requirements;

- 2. expressly stating that it is prepared to comply with 21A.44;
- 3. In the case of an aircraft restricted type-certificate, it is shown that the operational suitability data meets the applicable operational suitability data certification basis designated in accordance with 21A.17B.
- (b) By derogation from point (a)(3), the applicant may make a statement that compliance with the applicable operational suitability data certification basis will be declared after the date of issuance of the restricted type-certificate, but before the operational suitability data must be used by a training organisation or a European Union operator.
- (c) The engine or propeller installed in the aircraft, or both, shall:
 - 1. have a type-certificate issued or determined in accordance with this Regulation; or
 - 2. have been shown to be in compliance with the Certification Specifications necessary to ensure safe flight of the aircraft.'
- 10. in point 21A.31(a), point 3 is replaced by the following:
 - '3. An approved airworthiness limitations section of the instructions for continued airworthiness as defined by the applicable Certification Specifications; and'
- 11. in point 21A.33, point (a) is replaced by the following:
 - '(a) The applicant shall perform all inspections and tests necessary to show compliance with the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements.'
- 12. point 21A.41 is replaced by the following:

'21A.41 Type-certificate

The type-certificate and restricted type-certificate are both considered to include the type design, the operating limitations, the type-certificate data sheet for airworthiness and emissions, the applicable type-certification basis, and environmental protection requirements with which the Agency records compliance, and any other conditions or limitations prescribed for the product in the applicable Certification Specifications and environmental protection requirements. The aircraft type-certificate and restricted type-certificate, in addition, both include the applicable operational suitability data certification basis, the operational suitability data and the type-certificate data sheet for noise. The engine type-certificate data sheet includes the record of emission compliance.'

- 13. in point 21A.44, point (a) is replaced by the following:
 - (a) undertake the obligations laid down in 21A.3, 21A.3B, 21A.4, 21A.55, 21A.57, 21A.61 and 21A62; and, for this purpose, shall continue to meet the qualification requirements for eligibility under 21A.14; and
- 14. point 21A.55 is replaced by the following:

'21A.55 Record-keeping

All relevant design information, drawings and test reports, including inspection records for the product tested, shall be held by the type-certificate or restricted type-certificate holder at the disposal of the Agency and shall be retained in order to provide the information necessary to ensure the continued airworthiness, continued operational suitability and compliance with applicable environmental protection requirements of the product.' 15. point 21A.57 is replaced by the following:

'21A.57 Manuals

The holder of a type-certificate or restricted type-certificate shall produce, maintain and update master copies of all manuals required by the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements for the product, and provide copies, on request, to the Agency.'

16. the following point 21A.62 is added:

'21A.62 Availability of operational suitability data

The holder of the type-certificate or restricted type-certificate shall make available:

- (a) at least one set of complete operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known European Union operators of the aircraft, before the operational suitability data must be used by a training organisation or a European Union operator; and
- (b) any change to the operational suitability data to all known European Union operators of the aircraft; and
- (c) on request, the relevant data in (a) and (b) above, to:
 - 1. the competent authority responsible for verifying conformity with one or more elements of this set of operational suitability data; and
 - 2. any person required to comply with one or more elements of this set of operational suitability data.'
- 17. point 21A.90 is replaced by the following:

'21A.90 Scope

This Subpart establishes the procedure for the approval of changes to type-certificates, and establishes the rights and obligations of the applicants for, and holders of, those approvals. In this Subpart, references to type-certificates include type-certificate and restricted type-certificate.'

18. point 21A.91 is replaced by the following:

'21A.91 Classification of changes to a type-certificate

Changes to a type-certificate are classified as minor and major. A 'minor change' is one that has no appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, noise, fuel venting, exhaust emission, operational suitability data or other characteristics affecting the airworthiness of the product. Without prejudice to 21A.19, all other changes are 'major changes' under this Subpart. Major and minor changes shall be approved in accordance with 21A.95 or 21A.97, as appropriate, and shall be adequately identified.'

19. point 21A.92 is replaced by the following:

'21A.92 Eligibility

(a) Only the type-certificate holder may apply for approval of a major change to a type-certificate under this Subpart; all other applicants for a major change to a type-certificate shall apply under Subpart E.

- (b) Any natural or legal person may apply for approval of a minor change to a type-certificate under this Subpart.'
- 20. point 21A.93 is replaced by the following:

'21A.93 Application

An application for approval of a change to a type-certificate shall be made in a form and manner established by the Agency and shall include:

- (a) A description of the change identifying:
 - 1. All parts of the type-certificate and the approved manuals affected by the change; and
 - 2. The Certification Specifications and environmental protection requirements with which the change has been designed to comply in accordance with 21A.101.
- (b) Identification of any reinvestigations necessary to show compliance of the changed product with the applicable Certification Specifications and environmental protection requirements.
- (c) When the change affects the operational suitability data, the application shall include, or be supplemented after the initial application to include the necessary changes to the operational suitability data.'
- 21. point 21A.95 is replaced by the following:

'21A.95 Minor changes

Minor changes to a type-certificate shall be classified and approved either:

- (a) By the Agency; or
- (b) By an appropriately approved design organisation under a procedure agreed with the Agency.'
- 22. point 21A.97 is replaced by the following:

'21A.97 Major changes

- (a) An applicant for approval of a major change shall:
 - 1. Submit to the Agency substantiating data together with any necessary descriptive data for inclusion in the type design;
 - 2. Show that the changed product complies with applicable Certification Specifications, including the specifications for the operational suitability data as applicable, and environmental protection requirements, as specified in 21A.101;
 - 3. Declare that it has shown compliance with the applicable type-certification basis, and the operational suitability data certification basis as applicable, and environmental protection requirements and shall provide to the Agency the basis on which such a declaration is made;
 - 4. Where the applicant holds an appropriate design organisation approval, make the declaration of subparagraph (a)(3) according to the provisions of Subpart J;
 - 5. Comply with 21A.33 and, where applicable, 21A.35.

- (b) Approval of a major change to a type design certificate is limited to that or those specific configuration(s) in the type design upon which the change is made.'
- 22. point 21A.101 is replaced by the following:

'21A.101 Designation of applicable Certification Specifications and environmental protection requirements

- (a) An applicant for a change to a type-certificate shall demonstrate that the changed product complies with the Certification Specifications that are applicable to the changed product and that are in effect at the date of the application for the change, and with the applicable environmental protection requirements laid down in 21A.18.
- (b) By derogation from paragraph (a), an applicant may show that the changed product complies with an earlier amendment of the Certification Specifications defined in paragraph (a), and of any other Certification Specification the Agency finds is directly related. However, the earlier amended Certification Specifications may not precede the corresponding Certification Specifications incorporated by reference in the type-certificate. The applicant may show compliance with an earlier amendment of the Certification Specifications for any of the following:
 - 1. A change that the Agency finds not to be significant. In determining whether a specific change is significant, the Agency considers the change in context with all previous relevant design changes and all related revisions to the applicable Certification Specifications incorporated in the type-certificate for the product. Changes that meet one of the following criteria are automatically considered significant:
 - (i) The general configuration or the principles of construction are not retained;
 - (ii) The assumptions used for certification of the product to be changed do not remain valid.
 - 2. Each area, system, part or appliance that the Agency finds is not affected by the change.
 - 3. Each area, system, part or appliance that is affected by the change, for which the Agency finds that compliance with the Certification Specifications described in paragraph (a) would not contribute materially to the level of safety of the changed product or would be impractical.
- (c) An applicant for a change to an aircraft (other than a rotorcraft) of 2 722 kg (6 000 lbs) or less maximum weight or to a non-turbine rotorcraft of 1 361 kg (3 000 lbs) or less maximum weight may show that the changed product complies with the type-certification basis incorporated by reference in the type-certificate. However, if the Agency finds that the change is significant in an area, the Agency may designate compliance with an amendment to the type-certification basis incorporated by reference in the type-certificate in effect at the date of the application and any Certification Specification that the Agency finds is directly related, unless the Agency also finds that compliance with that amendment or Certification Specification would not contribute materially to the level of safety of the changed product or would be impractical.
- (d) If the Agency finds that the Certification Specifications in effect at the date of the application for the change do not provide adequate standards with respect to the

- proposed change, the applicant shall also comply with any special conditions, and amendments to those special conditions, prescribed under the provisions of 21A.16B, to provide a level of safety equivalent to that established in the Certification Specifications in effect at the date of the application for the change.
- (e) An application for a change to a type-certificate for large aeroplanes and large rotorcraft is effective for five years, and an application for a change to any other type-certificate is effective for three years. In a case where the change has not been approved, or it is clear that it will not be approved under the time limit established under this subparagraph, the applicant may:
 - 1. File a new application for a change to the type-certificate and comply with all the provisions of paragraph (a) applicable to an original application for a change; or
 - 2. File for an extension of the original application and comply with the provisions of paragraph (a) for an effective date of application, to be selected by the applicant, not earlier than the date which precedes the date of approval of the change by the time period established under this subparagraph for the original application for the change.
- (f) When the application for a change to a type-certificate for an aircraft includes, or is supplemented after the initial application to include changes to the operational suitability data, the operational suitability data certification basis shall be designated in accordance with points (a) through (d) above.'
- 23. point 21A.103 is replaced by the following:

'21A.103 Issue of approval

- (a) The applicant shall be entitled to have a major change to a type-certificate approved by the Agency after:
 - 1. Submitting the declaration referred to in 21A.97(a)(3); and
 - 2. It is shown that:
 - (i) The changed product meets the applicable Certification Specifications and environmental protection requirements, as specified in 21A.101;
 - (ii) Any airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety; and
 - (iii) No feature or characteristic makes the product unsafe for the uses for which certification is requested.
 - 3. In the case of a change affecting the operational suitability data, it is shown that the necessary changes to the operational suitability data meet the applicable operational suitability data certification basis designated in accordance with 21A.101(f).
 - 4. By derogation from point 3, a major change to an aircraft type-certificate may be approved before compliance with the applicable operational suitability data certification basis has been shown. In this case, the validity of the approval shall be conditioned to the applicant demonstrating compliance with the operational suitability data certification basis before that data must be used by a training organisation or a European Union operator. By derogation from

21A.97, the declaration referred to in point 1, shall state the date by which compliance will be shown.

- (b) A minor change to a type-certificate shall only be approved in accordance with 21A.95 if it is shown that the changed product meets the applicable Certification Specifications, as specified in 21A.101.'
- 24. point 21A.105 is replaced by the following:

'21A.105 Record-keeping

For each change, all relevant design information, drawings and test reports, including inspection records for the changed product tested, shall be held by the applicant at the disposal of the Agency and shall be retained in order to provide the information necessary to ensure the continued airworthiness, continued validity of the operational suitability data and compliance with applicable environmental protection requirements of the changed product.'

- 25. in point 21A.107, point (a) is replaced by the following:
 - (a) The holder of a minor change approval to a type-certificate shall furnish at least one set of the associated variations, if any, to the instructions for continued airworthiness of the product on which the minor change is to be installed, prepared in accordance with the applicable type-certification basis, to each known owner of one or more aircraft, engine, or propeller incorporating the minor change, upon its delivery, or upon issuance of the first certificate of airworthiness for the affected aircraft, whichever occurs later, and thereafter make those variations in instructions available, on request, to any other person required to comply with any of the terms of those instructions.
- 26. the following point 21A.108 is added:

21A.108 Availability of operational suitability data

In the case of a change affecting the operational suitability data, the holder of the minor change approval shall make available:

- (a) at least one set of changes to the operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known European Union operators of the changed aircraft, before the operational suitability data must be used by a training organisation or a European Union operator; and
- (b) any further change to the affected operational suitability data, to all known European Union operators of the changed aircraft; and
- (c) on request, the relevant parts of the changes in (a) and (b) above to:
 - 1. the competent authority responsible for verifying conformity with one or more elements of the affected operational suitability data; and
 - 2. any person required to comply with one or more elements of this set of operational suitability data.'
- 27. point 21A.109 is replaced by the following:

'21A.109 Obligations and EPA marking

The holder of a minor change approval to a type-certificate shall:

(a) undertake the obligations laid down in 21A.4, 21A.105, 21A.107 and 21A.108; and

- (b) specify the marking, including EPA (European Part Approval) letters, in accordance with 21A.804(a).'
- 28. point 21A.111 is replaced by the following:

'21A.111 Scope

This Subpart establishes the procedure for the approval of major changes to the type-certificate under supplemental type-certificate procedures, and establishes the rights and obligations of the applicants for, and holders of, those certificates.'

- 29. in point 21A.113, point (b) is replaced by the following:
 - '(b) An application for a supplemental type-certificate shall include the descriptions, identification and changes to the operational suitability data required by 21A.93. In addition, such an application shall include a justification that the information on which those identifications are based is adequate either from the applicant's own resources, or through an arrangement with the type-certificate holder.'
- 30. in point 21A.118A, point (a)1 is replaced by the following:
 - '1. Laid down in 21A.3, 21A.3B, 21A.4, 21A.105, 21A.119, 21A.120A and 21A.120B;'
- 31. point 21A.119 is replaced by the following:

'21A.119 Manuals

The holder of a supplemental type-certificate shall produce, maintain, and update master copies of variations in the manuals required by the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements for the product, necessary to cover the changes introduced under the supplemental type-certificate, and furnish copies of these manuals to the Agency on request.'

32. the title of point 21A.120 is replaced by the following:

'21A.120A Instructions for continued airworthiness'

33. the following point 21A.120B is added:

'21A.120B Availability of operational suitability data

In the case of a change affecting the operational suitability data, the holder of the supplemental type-certificate shall make available:

- (a) at least one set of changes to the operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known European Union operators of the changed aircraft, before the operational suitability data must be used by a training organisation or a European Union operator; and
- (b) any further change to the affected operational suitability data, to all known European Union operators of the changed aircraft; and
- (c) on request, the relevant parts of the changes in (a) and (b) above, to:
 - 1. the competent authority responsible for verifying conformity with one or more elements of the affected operational suitability data; and
 - 2. any person required to comply with one or more elements of this set of operational suitability data.'
- 34. in point 21A.239, point (a)1 is replaced by the following:

- '1. To ensure that the design of the products, parts and appliances or the design change thereof, comply with the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements; and'
- 35. in point 21A.245, points (a) and (b) are replaced by the following:
 - '(a) The staff in all technical departments are of sufficient numbers and experience and have been given appropriate authority to be able to discharge their allocated responsibilities and that these, together with the accommodation, facilities and equipment are adequate to enable the staff to achieve the airworthiness, operational suitability and environmental protection objectives for the product.
 - (b) There is full and efficient coordination between departments and within departments in respect of airworthiness, operational suitability and environmental protection matters.'
- 36. point 21A.247 is replaced by the following:

'21A.247 Changes in design assurance system

After the issue of a design organisation approval, each change to the design assurance system that is significant to the showing of compliance or to the airworthiness, operational suitability and environmental protection of the product, shall be approved by the Agency. An application for approval shall be submitted in writing to the Agency and the design organisation shall demonstrate to the Agency, on the basis of submission of proposed changes to the handbook, and before implementation of the change, that it will continue to comply with this Subpart after implementation.'

37. point 21A.251 is replaced by the following:

'21A.251 Terms of approval

The terms of approval shall identify the types of design work, the categories of products, parts and appliances for which the design organisation holds a design organisation approval, and the functions and duties that the organisation is approved to perform in regard to the airworthiness, operational suitability and characteristics of noise, fuel venting and exhaust emissions of products. For design organisation approval covering type-certification or ETSO authorisation for Auxiliary Power Unit (APU), the terms of approval shall contain in addition the list of products or APU. Those terms shall be issued as part of a design organisation approval.'

- 38. in point 21A.263, point (c) is replaced by the following:
 - '(c) The holder of a design organisation approval shall be entitled, within its terms of approval and under the relevant procedures of the design assurance system:
 - 1. to classify changes to the type-certificate and repairs as 'major' or 'minor'.
 - 2. to approve minor changes to the type-certificate and minor repairs.'
- 39. the following point 21B.70 is added:

'21B.70 Approval of changes to type-certificates

The approval of the changes to the operational suitability data is included in the approval of the change to the type-certificate. However, the Agency shall use a separate classification and approval process for administering changes to operational suitability data.'