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Delegations will find attached Commission document D028103/02

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Brussels, **XXX**
[...](2013) **XXX** draft

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

of XXX

amending Commission Regulation (EU) No 748/2012 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)

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

of XXX

amending Commission Regulation (EU) No 748/2012 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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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, and in particular Article 5(5) thereof,

Whereas:

- (1) Article 5 of Regulation (EC) No 216/2008 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 (the ‘Agency’) found that it was necessary to amend Commission Regulation (EU) No 748/2012² in order to allow the Agency to approve operational suitability data as part of the type-certification process.
- (3) The Agency prepared draft implementing rules on the concept of operational suitability data and submitted them as an opinion³ to the Commission in accordance with Article 19(1) of Regulation (EC) No 216/2008.
- (4) Article 5 of Regulation (EU) No 748/2012 derives from Article 2c of Regulation (EC) No 1702/2003⁴. Article 2c of Regulation (EC) No 1702/2003 was introduced for a temporary grandfathering of types that were not grandfathered by Article 2a of Regulation (EC) No 1702/2003. As this transitional regime ended definitively on 28 September 2009, Article 5 of Regulation (EU) No 748/2012 should be deleted.

¹ OJ L 79, 19.3.2008, p. 1.

² OJ L 224, 21.8.2012, p. 1.

³ Opinion No 07/2011 of the European Aviation Safety Agency of 13th December 2011, available at <http://easa.europa.eu/official-publication/agency-opinions.php>.

⁴ OJ L 243, 27.9.2003, p. 6

- (5) In order to avoid confusion and legal uncertainty with regard to points 21.A.16A, 21.A.16B, 21.A.17, 21.A.31 and 21.A.101 of Annex I (Part 21) to Regulation (EU) No 748/2012, it is necessary to replace the references to 'airworthiness codes' with 'certification specifications'.
- (6) In order to avoid confusion and legal uncertainty with regard to points 21.A.4, 21.A.90A, 21.A.90B, 21.A.91, 21.A.92, 21.A.93, 21.A.95, 21.A.97, 21.A.103, 21.A.107, 21.A.109, 21.A.111, 21.A.263 and 21.A.435 of Annex I (Part 21) to Regulation (EU) No 748/2012, it is necessary to replace the references to 'type design' with 'type-certificate'.
- (7) Regulation (EU) 748/2012 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 65 of Regulation (EC) No 216/2008,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 748/2012 is amended as follows:

- (1) Article 3 is amended as follows:
 - (a) In point (1)(a), point (i) is replaced by the following:
 - "(i) its type-certification basis was:
 - the JAA type-certification basis, for products that have been certificated under JAA procedures, as defined in their JAA data sheet, or
 - for other products, the type-certification basis as defined in the type-certificate data sheet of the State of design, if that State of design was:
 - a Member State, unless the Agency determines, taking into account, in particular, certification specifications used and service experience, that such type-certification basis does not provide for a level of safety equivalent to that required by Regulation (EC) No 216/2008 and this Regulation, or
 - a State with which a Member State had concluded a bilateral airworthiness agreement or similar arrangement under which such products have been certificated on the basis of the certification specifications of that State of design, unless the Agency determines that such certification specifications or service experience or the safety system of that State of design do not provide for a level of safety equivalent to that required by Regulation (EC) No 216/2008 and this Regulation.

The Agency shall make a first evaluation of the implication of the provisions of the second indent in view of producing an opinion to the Commission including possible amendments to this Regulation;"

(b) In point (2), points (c) and (d) are replaced by the following:

"(c) by way of derogation from point 21.A.17A(a) of Annex I (Part 21), the type-certification basis shall be that established by the JAA or, where applicable, the Member State at the date of application for the approval;"

"(d) compliance findings made under JAA or Member State procedures shall be deemed to have been made by the Agency for the purpose of complying with points 21.A.20(a) and (d) of Annex I (Part 21).";

(2) Article 5 is deleted;

(3) The following Article 7a is inserted:

"Article 7a Operational suitability data

1. The holder of an aircraft type-certificate issued before (...) [The Publications Office will insert the date of entry into force of this Regulation.] intending to deliver a new aircraft to an EU operator on or after (...) [The Publications Office will insert the date of entry into force of this Regulation.] shall obtain approval in accordance with point 21.A.21(e) of Annex I (Part 21) 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 not later than 18 December 2015 or before the aircraft is operated by an EU operator, whichever is the latest. The operational suitability data may be limited to the model which is delivered.

2. The applicant for an aircraft type-certificate for which the application was filed before (...) [The Publications Office will insert the date of entry into force of this Regulation.] and for which a type-certificate is not issued before (...) [The Publications Office will insert the date of entry into force of this Regulation.] shall obtain approval in accordance with point 21.A.21(e) of Annex I (Part 21) 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 not later than 18 December 2015 or before the aircraft is operated by an EU operator, whichever is the latest. Compliance findings made by the authorities in Operational Evaluation Board processes conducted under the responsibility of the JAA or the Agency before the entry into force of this Regulation shall be accepted by the Agency without further verification.

3. Operational Evaluation Board reports and master minimum equipment lists 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 point 21.A.21(e) of Annex I (Part 21) and shall be included in the relevant type-certificate. Before 18 June 2014 the relevant type-certificate holders shall propose the Agency a division of the operational suitability data in mandatory data and non-mandatory data.

4. Holders of a type-certificate including operational suitability data shall be required to obtain approval of an extension of the scope of their design organisation approval or procedures alternative to design organisation approval, as applicable, to include operational suitability aspects before 18 December 2015.";

(4) Annex I (Part 21) is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Points 16-34 and point 43 of the Annex shall apply to applicants for the approval of a change to a type-certificate as well as applicants for a supplemental type-certificate from 19 December 2016.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President

ANNEX

Annex I (Part 21) is amended as follows:

(1) Point 21.A.4 is replaced by the following:

"21.A.4 Coordination between design and production

Each holder of a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, approval of a change to type-certificate or approval of a repair design, shall collaborate with the production organisation as necessary to ensure:

- (a) the satisfactory coordination of design and production required by 21A.122, 21A.130(b)(3) and (4), 21A.133 and 21A.165(c)(2) and (3) as appropriate, and
- (b) the proper support of the continued airworthiness of the product, part or appliance.";

(2) In point 21.A.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 with, after the initial application, 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;
- 5. the master minimum equipment list; and
- 6 other type-related operational suitability elements.";

(3) Point 21.A.16A is replaced by the following:

"21.A.16A Certification specifications

The Agency shall issue in accordance with Article 19 of Regulation (EC) No 216/2008 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 Regulation (EC) No 216/2008. 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 21.A.16B is replaced by the following:

"21.A.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 shall 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 21.A.17 is amended as follows:

(a) The title is replaced by the following:

"21.A.17A Type-certification basis";

(b) In point (a), point (1) is replaced by the following:

"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 certification specifications of later effective amendments is chosen by the applicant or required under points (c) and (d);";

(c) In point (c), point (2) is replaced by the following:

"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 point (b) for the original application.";

(6) The following point 21.A.17B is inserted:

"21.A.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 point 21.A.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 Regulation (EC) 216/2008; or
 - (ii) compliance with certification specifications of later effective amendments is chosen by the applicant;
 2. any special condition prescribed in accordance with point 21.A.16B(a).
- (b) If an applicant chooses 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 certification specification that the Agency finds is directly related.";
- (7) Point 21.A.20 is amended as follows:
- (a) The title is replaced by the following:
- "Compliance with the type-certification basis, operational suitability data certification basis and environmental protection requirements"**;
- (b) Point (a) is replaced by the following:
- "(a) The applicant for a type-certificate or a restricted type-certificate shall demonstrate compliance with the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements and shall provide the Agency with the means by which such compliance has been demonstrated.";
- (8) Point 21.A.21 is amended as follows:
- (a) In point (c), point (1) is replaced by the following:
- "1. the product to be certificated meets the applicable type-certification basis and environmental protection requirements designated in accordance with point 21.A.17A and 21.A.18;"
- (b) The following points (e) and (f) are added:
- "(e) In the case of an aircraft type-certificate, it is demonstrated that the operational suitability data meets the applicable operational suitability data certification basis designated in accordance with 21.A.17B.
- (f) By derogation from point (e), and at the request of the applicant included in the declaration referred to in point 21.A.20(d), an aircraft type-certificate may be issued before compliance with the applicable

operational suitability data certification basis has been demonstrated, subject to the applicant demonstrating compliance with the operational suitability data certification basis before the operational suitability data must actually be used.";

(9) Point 21.A.23 is replaced by the following:

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

- (a) For an aircraft that does not meet the provisions of point 21.A.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 point 21.A.44;
 3. in the case of an aircraft restricted type-certificate, it is demonstrated that the operational suitability data meets the applicable operational suitability data certification basis designated in accordance with point 21.A.17B.
- (b) By derogation from point (3) of point (a), and at the request of the applicant included in the declaration referred to in point 21.A.20(d), a restricted type-certificate may be issued before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to the applicant demonstrating compliance with the operational suitability data certification basis before the operational suitability data must actually be used.
- (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 21.A.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) Point 21A.41 is replaced by the following:

"21.A.41 Type-certificate

The type-certificate and restricted type-certificate shall 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, shall 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 shall include the record of emission compliance.";

(12) In point 21.A.44, point (a) is replaced by the following:

"(a) undertake the obligations laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.55, 21.A.57, 21.A.61 and 21.A.62; and, for this purpose, shall continue to meet the qualification requirements for eligibility under point 21.A.14; and";

(13) Point 21.A.55 is replaced by the following:

"21.A.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 validity of the operational suitability data and compliance with applicable environmental protection requirements of the product.";

(14) Point 21.A.57 is replaced by the following:

"21.A.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.";

(15) The following point 21.A.62 is added to Subpart B:

"21.A.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 EU operators of the aircraft, before the operational suitability data must be used by a training organisation or an EU operator; and
- (b) any change to the operational suitability data to all known EU operators of the aircraft; and
- (c) on request, the relevant data referred to in points (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.";

(16) Point 21.A.90A is replaced by the following:

"21.A.90A 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. This Subpart also defines standard changes that are not subject to an approval process under this Subpart. In this Subpart, references to type-certificates include type-certificate and restricted type-certificate.";

(17) In point 21.A.90B, point (a) is replaced by the following:

"(a) Standard changes are changes to a type-certificate:

1. in relation to:
 - (i) aeroplanes of 5 700 kg Maximum Take-Off Mass (MTOM) or less;
 - (ii) rotorcraft of 3 175 kg MTOM or less;
 - (iii) sailplanes, powered sailplanes, balloons and airships, as defined in ELA1 or ELA2,
2. that follow design data included in certification specifications issued by the Agency, containing acceptable methods, techniques and practices for carrying out and identifying standard changes, including the associated instructions for continuing airworthiness; and
3. that are not in conflict with TC holders data.";

(18) Point 21.A.91 is replaced by the following:

"21.A.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 point 21.A.19, all other changes are ‘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.";

(19) Point 21.A.92 is replaced by the following:

"21.A.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 21.A.93 is replaced by the following:

"21.A.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 design 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 point 21.A.101.

(b) Identification of any re-investigations 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 21.A.95 is replaced by the following:

"21.A.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) In point 21.A.97, point (b) is replaced by the following:

"(b) Approval of a major change in a type-certificate is limited to that or those specific configuration(s) in the type-certificate upon which the change is made.";

(23) Point 21.A.101 is replaced by the following:

"21.A.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, unless compliance with certification specifications

of later effective amendments is chosen by the applicant or required under points (e) and (f), and with the applicable environmental protection requirements laid down in point 21.A.18.

- (b) By derogation from point (a), an applicant may show that the changed product complies with an earlier amendment of the certification specifications referred to in point (a), and of any other certification specification the Agency finds is directly related. However, the earlier amended certification specifications shall 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 referred to in point (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 point 21.A.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 point, the applicant may:
 - 1. file a new application for a change to the type-certificate and comply with all the provisions of point (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 point (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 point for the original application for the change.
- (f) If an applicant chooses to comply with a certification specification of an amendment to the certification specifications that is effective after the filing of the application for a change to a type, the applicant shall also comply with any other certification specification that the Agency finds is directly related.
- (g) 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), (b), (c), (d) and (f) above.";

(24) Point 21.A.103 is replaced by the following:

"21.A.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 point 21.A.20(d); and
 - 2. it is demonstrated that:
 - (i) the changed product meets the applicable certification specifications and environmental protection requirements, as specified in point 21.A.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 demonstrated that the necessary changes to the operational suitability data meet the applicable operational suitability data certification basis designated in accordance with point 21.A.101(g);

4. by derogation from point 3, and at the request of the applicant included in the declaration referred to in point 21.A.20(d), a major change to an aircraft type-certificate may be approved before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to the applicant demonstrating compliance with the operational suitability data certification basis before the operational suitability data must actually be used.

(b) A minor change to a type-certificate shall only be approved in accordance with point 21.A.95 if it is shown that the changed product meets the applicable certification specifications, as specified in point 21.A.101.";

(25) Point 21.A.105 is replaced by the following:

"21.A.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.";

(26) In point 21.A.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.";

(27) The following point 21.A.108 is inserted:

"21.A.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 EU operators of the changed aircraft, before the operational suitability data must be used by a training organisation or an EU operator; and

(b) any further change to the affected operational suitability data, to all known EU operators of the changed aircraft; and

(c) on request, the relevant parts of the changes in points (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.";

(28) Point 21.A.109 is replaced by the following:

"21.A.109 Obligations and EPA marking

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

- (a) undertake the obligations laid down in points 21.A.4, 21.A.105, 21.A.107 and 21.A.108; and
- (b) specify the marking, including EPA (European Part Approval) letters, in accordance with point 21.A.804(a).";

(29) Point 21.A.111 is replaced by the following:

"21.A.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.";

(30) In point 21.A.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 point 21.A.93. In addition, such an application shall include a justification that the information on which those elements are based is adequate either from the applicant's own resources, or through an arrangement with the type-certificate holder.";

(31) In point 21.A.118A, point (a) is replaced by the following:

"(a) undertake the obligations:

1. laid down in points 21.A.3A, 21.A.3B, 21.A.4, 21.A.105, 21.A.119, 21.A.120A and 21.A.120B;
2. implicit in the collaboration with the type-certificate holder under point 21.A.115(d)(2);

and for this purpose continue to meet the criteria of point 21.A.112B;"

(32) Point 21.A.119 is replaced by the following:

"21.A.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 those manuals to the Agency on request.";

- (33) In point 21.A.120, the title is replaced by the following:

"21.A.120A Instructions for continued airworthiness";

- (34) The following point 21.A.120B is added to Subpart E:

"21.A.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 EU operators of the changed aircraft, before the operational suitability data must be used by a training organisation or an EU operator; and
- (b) any further change to the affected operational suitability data, to all known EU operators of the changed aircraft; and
- (c) on request, the relevant parts of the changes in points (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.";

- (35) In point 21.A.174(b)(2), point (iii) is replaced by the following:

"(iii) the flight manual, when required by the applicable certification specifications for the particular aircraft;"

- (36) In point 21.A.239(a), point (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";

- (37) Point 21.A.245 is replaced by the following:

"21.A.245 Approval requirements

The design organisation shall demonstrate, on the basis of the information submitted in accordance with point 21.A.243 that, in addition to complying with point 21.A.239:

- (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 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.";

(38) Point 21.A.247 is replaced by the following:

"21.A.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.";

(39) 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 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.";

(40) Point 21.A.263 is amended as follows:

(a) Point (2) of point (b) is replaced by the following:

"2. a type-certificate or approval of a major change to a type-certificate; or";

(b) Points (1) and (2) of point (c) are replaced by the following:

"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;"

(41) In point 21.A.435, point (a) is replaced by the following:

"(a) A repair may be 'major' or 'minor'. The classification shall be made in accordance with the criteria of point 21.A.91 for a change in the type-certificate."

(42) In point 21.A.604, point (a) is replaced by the following:

"(a) points 21.A.15, 21.A.16B, 21.A.17A, 21.A.17B, 21.A.20, 21.A.21, 21.A.31, 21.A.33, 21.A.44 shall apply by way of derogation from points 21.A.603, 21.A.606(c), 21.A.610 and 21.A.615, except that an ETSO Authorisation shall be issued in accordance with 21.A.606 instead of the type-certificate;"

(43) In Section B of Annex I (Part 21), Subpart D is amended as follows:

(a) The existing statement "Administrative procedures established by the Agency shall apply" is deleted;

(b) The following point 21.B.70 is added:

"21.B.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.";

(44) In point 21.B.326(b)(1), point (iii) is replaced by the following:

"(iii) the aircraft has been inspected in accordance with the applicable provisions of Annex I (Part M) of Regulation (EC) No 2042/2003;"

(45) In point 21.B.327(a)(2)(i), point (C) is replaced by the following:

"(C) the aircraft has been inspected in accordance with the applicable provisions of Annex I (Part M) of Regulation (EC) No 2042/2003;"

(46) In Appendix I, blocks 14a, 14b, 14c, 14d and 14e of the EASA Form 1 shall be in grey shading;

(47) In Appendix I, the introductory phrase to the instructions for the use of EASA Form 1 is replaced by following:

"These instructions relate only to the use of the EASA Form 1 for production purposes. Attention is drawn to Appendix II to Annex I (Part M) of Regulation (EC) No 2042/2003 which covers the use of the EASA Form 1 for maintenance purposes".