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⁽¹⁾ Text with EEA relevance.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2019/897

of 12 March 2019

amending Regulation (EU) No 748/2012 as regards the inclusion of risk-based compliance verification in Annex I and the implementation of requirements for environmental protection**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ⁽¹⁾, and in particular Article 19(1) thereof,

Whereas:

- (1) In accordance with Article 77 of Regulation (EU) 2018/1139, the European Union Aviation Safety Agency ('the Agency') is to carry out on behalf of Member States the functions and tasks of the state of design, manufacture or registry related to design certification. In accordance with Article 77(1)(a) in conjunction with Article 62(2)(a) of Regulation (EU) 2018/1139 the Agency is to receive and assess the applications made to it and issues the appropriate certificates. For this purpose the Agency is to establish and notify to the applicant the certification basis, applicable environmental protection requirements and operational suitability data certification basis.
- (2) Under Commission Regulation (EU) No 748/2012 ⁽²⁾ an applicant is to receive a certificate issued by the Agency after it is shown that the product to be certified meets the applicable certification basis including the applicable airworthiness certification specifications and environmental protection requirements. Applicants for those certificates are to demonstrate full compliance with all aspects of the established certification basis. In accordance with Article 83 of Regulation (EU) 2018/1139, the Agency itself, or through national aviation authorities or qualified entities, is to carry out investigations necessary for the performance of its certification tasks. The Agency assesses the applications but it is not required to carry out exhaustive investigation in all cases pursuant to Article 83 of Regulation (EU) 2018/1139. Therefore, in order to better mitigate any safety risks due to selective investigations and to improve the effectiveness, transparency and predictability of the certification process, certain selection criteria should be provided to allow determining which compliance demonstrations should be verified by the Agency and how exhaustively. Those criteria should be based on the safety oversight and management principles set out in Annex 19 to the Convention on International Civil Aviation ('the Chicago Convention').
- (3) Furthermore, under Regulation (EU) No 748/2012 holders of design organisation approvals are to take certain certification decisions, instead of the Agency, in line with their terms of approval and under the relevant

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ Commission Regulation (EU) No 748/2012 of 3 August 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 (OJ L 224, 21.8.2012, p. 1).

procedures of the design assurance system. Based on the experience with those existing privileges and in order to reduce administrative burden, while considering the risks to aviation safety and environmental protection requirements, holders of design organisation approvals should also be entitled to certify certain major changes to type certificates and issue certain supplemental type certificates. In order to limit risks to aviation safety and having regard to environmental protection requirements, those new privileges should only relate to certification of major changes of a limited novelty and should be granted only to those holders who can correctly exercise those new privileges. The latter should be demonstrated through showing a satisfactory performance in previous similar major changes with the involvement of the Agency.

- (4) For reasons of clarity, Annex I to Regulation (EU) No 748/2012 should be amended in such a manner that section A sets out the requirements applicable only to applicants for, and holders of, any certificate issued or to be issued in accordance with that Annex and its section B sets out the requirements applicable only to the competent authorities, including the Agency.
- (5) Air operators are to conduct check flights after maintenance to ensure the proper functioning of certain aircraft systems that cannot be verified on the ground. Accidents or serious incidents encountered in the past during those flights reveal that certain maintenance check flights should not be conducted under a certificate of airworthiness (or restricted certificate of airworthiness) but should require a permit to fly. Therefore, flying an aircraft for troubleshooting purposes or to check the functioning of one or more systems, parts or appliances after maintenance should be added to the list of flights for which a permit to fly is required.
- (6) Certain inconsistencies of Regulation (EU) No 748/2012 with Regulation (EU) 2018/1139 as regards the content of the type-certification basis and the notification process should be corrected.
- (7) Article 9(2) of Regulation (EU) 2018/1139 requires that, as regards noise and emissions, aircraft and their engines, propellers, parts and non-installed equipment are to comply with the environmental protection requirements contained in Amendment 12 of Volume I, in Amendment 9 of Volume II, and in the initial issue of Volume III of Annex 16 to the Chicago Convention, as applicable on 1 January 2018.
- (8) Therefore, Annex I to Regulation (EU) No 748/2012 should be adapted to reflect the environmental protection requirements contained in Annex 16 of the Chicago Convention. Furthermore, since Annex 16 of the Chicago Convention provides for exemptions from the environmental protection requirements for specific engines or aircraft, Regulation (EU) No 748/2012 should provide the possibility for production organisations to apply to their competent authority for exemptions from the environmental requirements.
- (9) In addition, in order to eliminate technical issues arising from the application of the standards and recommended practices and related guidance for aircraft and engine certification, certain provisions of Regulation (EU) No 748/2012 should be amended in order to improve their clarity.
- (10) Regulation (EU) No 748/2012 should therefore be amended accordingly.
- (11) It is necessary to provide sufficient time to all parties concerned to adapt to the amended regulatory framework created as a consequence of the measures laid down in this Regulation.
- (12) The measures provided for in this Regulation are based on the opinions 07/2016 ⁽³⁾, 01/2017 ⁽⁴⁾ and 09/2017 ⁽⁵⁾ issued by the Agency in accordance with Article 76(1) of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

Article 1

- (1) In Article 1(2), the following point (k) is added:

‘(k) “Operational Suitability Data (OSD)” means data, which are part of an aircraft type-certificate, restricted type-certificate or supplemental type-certificate, consisting of all of the following:

- (i) the minimum syllabus of pilot type rating training, including determination of type rating;

⁽³⁾ Opinion 07/2016: Embodiment of level of involvement requirements into Part-21

⁽⁴⁾ Opinion 01/2017: Maintenance check flights

⁽⁵⁾ Opinion 09/2017: Implementation of the CAEP/10 amendments on climate change, emissions and noise

- (ii) the definition of scope of the aircraft validation source data to support the objective qualification of simulators or the provisional data to support their interim qualification;
- (iii) the minimum syllabus of maintenance certifying staff type rating training, including determination of type rating;
- (iv) determination of type or variant for cabin crew and type specific data for cabin crew;
- (v) the master minimum equipment list;

(2) In Article 9, the following paragraph 4 is added:

‘4. By way of derogation from paragraph 1, the production organisation may apply to the competent authority for exemptions from the environmental requirements referred to in the first subparagraph of Article 9(2) of Regulation (EU) 2018/1139 (*).

(*) Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).’;

(3) Annex I to Regulation (EU) No 748/2012 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*.

It shall apply from [OP please insert date: 9 months after date of entry into force], with the exception of Article 1(2) and point 11, points 13 to 14, points 23 to 26, point 28, point 30, point 21.B.85 in point 40 and point 43 of Annex which shall apply from [OP please insert date of entry into force].

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

Done at Brussels, 12 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

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

- (1) the table of contents is replaced by the following:

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(2) point 21.A.14 is amended as follows:

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

'(a) An applicant for a type-certificate or restricted type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.;

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

'(c) By way of derogation from point (a), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.15(b), where the product to be certified is:

1. an ELA1 aircraft; or
2. an engine or propeller installed in ELA1 aircraft.;

(3) point 21.A.15 is amended as follows:

(a) points (b), (c) and (d) are replaced by the following:

'(b) An application for a type-certificate or restricted type-certificate shall include, as a minimum, preliminary descriptive data of the product, the intended use of the product and the kind of operations for which certification is requested. In addition, it shall include, or be supplemented after the initial application, a certification programme for the demonstration of compliance in accordance with point 21.A.20, consisting of:

1. a detailed description of the type design, including all the configurations to be certified;
2. the proposed operating characteristics and limitations;
3. the intended use of the product and the kind of operations for which certification is requested;

4. a proposal for the initial type-certification basis, operational suitability data certification basis and environmental protection requirements, prepared in accordance with the requirements and options specified in points 21.B.80, 21.B.82 and 21.B.85;
 5. a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including a proposal for the means of compliance and related compliance documents;
 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 product safety or environmental protection. The proposed assessment shall take into account at least the elements set out in subpoints (1) to (4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and
 7. a project schedule including major milestones.
- (c) After its initial submission to the Agency, the certification programme shall be updated by the applicant when there are changes to the certification project affecting any of the points 1 to 7 of point (b).
- (d) An application for a type-certificate or restricted type-certificate for an aircraft shall include, or be supplemented after the initial application, an application supplement for approval of the operational suitability data.;
- (b) the following points (e) and (f) are added:
- '(e) An application for a type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft shall be valid for five years and an application for any other type-certificate or restricted type-certificate shall be valid for three years, unless the applicant demonstrates at the time of application that its product requires a longer time period to demonstrate and declare compliance and the Agency agrees to that longer time period.
- (f) In the case where a type-certificate or restricted type-certificate has not been issued, or it is evident that it will not be issued, within the time limit provided for in point (e), the applicant may:
1. submit a new application and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency in accordance with points 21.B.80, 21.B.82 and 21.B.85 for the date of the new application; or
 2. apply for an extension of the time period provided for in point (e) and propose a new date for the issuance of the type-certificate or restricted type-certificate. In that case, the applicant shall comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency in accordance with points 21.B.80, 21.B.82 and 21.B.85 for a date to be selected by the applicant. However, that date shall not precede the new date proposed by the applicant for the issuance of the type-certificate or restricted type-certificate by more than five years for an application for a type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft, and by more than three years for an application for any other type-certificate or restricted type certificate.;
- (4) point 21.A.16A is deleted;
- (5) point 21.A.16B is deleted;
- (6) point 21.A.17A is deleted;
- (7) point 21.A.17B is deleted;
- (8) point 21.A.18 is deleted;
- (9) points 21.A.20 and 21.A.21 are replaced by the following:

'21.A.20 Demonstration of compliance with the type certification basis, operational suitability data certification basis and environmental protection requirements

- (a) Following the acceptance of the certification programme by the Agency, the applicant shall demonstrate compliance with the type certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified to the applicant by the Agency in accordance with points 21.B.80, 21.B.82, 21.B.85, and shall provide the Agency with the means by which such compliance has been demonstrated.

- (b) The applicant shall report to the Agency any difficulty or event encountered during the process of demonstration of compliance that may have an appreciable effect on the risk assessment under point 21.A.15(b)(6) or on the certification programme, or may otherwise necessitate a change to the level of involvement of the Agency previously notified to the applicant in accordance with point 21.B.100(c).
- (c) The applicant shall record justifications of compliance within the compliance documents as referred to in the certification programme.
- (d) After completion of all demonstrations of compliance in accordance with the certification programme, including any inspections and tests in accordance with point 21.A.33, and after all flight tests in accordance with point 21.A.35, the applicant shall declare that:
 - 1. it has demonstrated compliance with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency, following the certification programme as accepted by the Agency; and
 - 2. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.
- (e) The applicant shall submit to the Agency the declaration of compliance provided for in point (d). Where the applicant holds an appropriate design organisation approval, the declaration of compliance shall be made in accordance with Subpart J and submitted to the Agency.

21.A.21 Requirements for the issuance of a type certificate or restricted type certificate

- (a) In order to be issued a product type certificate or, when the aircraft does not meet the essential requirements of Annex II to Regulation (EU) 2018/1139 an aircraft restricted type certificate, the applicant shall:
 - 1. demonstrate its capability in accordance with point 21.A.14;
 - 2. comply with point 21.A.20;
 - 3. demonstrate that the engine and propeller, if installed in the aircraft:
 - (A) have a type-certificate issued or determined in accordance with this Regulation; or
 - (B) have been demonstrated to be in compliance with the aircraft type-certification basis established and the environmental protection requirements designated and notified by the Agency as necessary to ensure the safe flight of the aircraft.
 - (b) By derogation from point (a)(2), at the applicant's request included in the declaration referred to in point 21.A.20(d), the applicant is entitled to have the aircraft type-certificate or restricted type-certificate issued before the applicant has demonstrated compliance with the operational suitability data certification basis, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.;
- (10) point 21.A.23 is deleted;
- (11) in point 21.A.31(a), point 4 is replaced by the following:
- ‘4. any other data allowing by comparison the determination of the airworthiness and, if relevant, the environmental characteristics of later products of the same type.’;
- (12) point 21.A.33 is replaced by the following:

‘21.A.33 Inspections and tests

- (a) (Reserved)
- (b) Before each test is undertaken during the demonstration of compliance required by point 21.A.20, the applicant shall have verified:
 - 1. for the test specimen, that:
 - (i) the materials and processes adequately conform to the specifications for the proposed type design;
 - (ii) the parts of the products adequately conform to the drawings in the proposed type design; and
 - (iii) the manufacturing processes, construction and assembly adequately conform to those specified in the proposed type design; and
 - 2. for the test and measuring equipment to be used for the test, that those are adequate for the test and appropriately calibrated.

- (c) On the basis of the verifications carried out in accordance with point (b), the applicant shall issue a statement of conformity listing any potential non-conformity, together with a justification that this will not affect the test results, and shall allow the Agency to make an inspection it considers necessary to check the validity of that statement.
- (d) The applicant shall allow the Agency to:
 - 1. review any data and information related to the demonstration of compliance; and
 - 2. witness or carry out any test or inspection conducted for the purpose of the demonstration of compliance.
- (e) For all the tests and inspections witnessed or carried out by the Agency in accordance with point (d)(2):
 - 1. the applicant shall submit to the Agency a statement of conformity provided for in point (c); and
 - 2. no change that affects the validity of the statement of conformity shall be made to the test specimen, or the test and measuring equipment, between the time the statement of conformity provided for in point (c) was issued and the time the test specimen is presented to the Agency for test.;

(13) point 21.A.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 shall include in addition the applicable operational suitability data certification basis, the operational suitability data and the type-certificate data sheet for noise. The aircraft type-certificate and restricted type-certificate data sheet shall include the record of CO₂ emissions compliance and the engine type-certificate data sheet shall include the record of exhaust emissions compliance.’;

(14) 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” has no appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, operational suitability data, or other characteristics affecting the airworthiness of the product or its environmental characteristics. 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.’

(15) point 21.A.93 is replaced by the following:

‘21.A.93 Application

- (a) An application for approval of a change to a type-certificate shall be made in a form and manner established by the Agency.
- (b) An application shall include, or be supplemented after the initial application, a certification programme for the demonstration of compliance in accordance with point 21.A.20, consisting of:
 - 1. a description of the change identifying:
 - (i) the configuration(s) of the product in the type certificate upon which the change is to be made;
 - (ii) all areas of the product in the type-certificate, including the approved manuals, that are changed or affected by the change; and
 - (iii) when the change affects the operational suitability data, any necessary changes to the operational suitability data;
 - 2. an identification of any reinvestigations necessary to demonstrate compliance of the change and areas affected by the change with the type-certification basis, operational suitability data certification basis and environmental protection requirements; and

3. for a major change to a type-certificate:
 - (i) a proposal for the initial type-certification basis, operational suitability data certification basis and environmental protection requirements, prepared in accordance with the requirements and options specified in point 21.A.101;
 - (ii) a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including a proposal for the means of compliance and related compliance documents;
 - (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 type-certification basis, operational suitability data certification basis or environmental protection requirements and the potential impact of that non-compliance on product safety or environmental protection. The proposed assessment shall take into account at least the elements set out in subpoints (1)–(4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and
 - (iv) a project schedule including major milestones.
 - (c) An application for a change to a type-certificate of a large aeroplane or a large rotorcraft shall be valid for five years and an application for a change to any other type-certificate shall be valid for three years. In the case where the change has not been approved, or it is evident that it will not be approved, within the time limit provided for in this point, the applicant may:
 1. submit a new application for a change to the type-certificate and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101 and notified in accordance with point 21.B.105 for the date of the new application; or
 2. apply for an extension of the time period provided for in the first sentence of point (c) for the original application and propose a new date for the issuance of the approval. In that case, the applicant shall comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101 and notified in accordance with point 21.B.105, for a date to be selected by the applicant. However, that date shall not precede the new date proposed by the applicant for the issuance of the approval by more than five years for an application for a type-certificate or restricted type-certificate for a large aeroplane or a large rotorcraft, and by more than three years for an application for any other type-certificate or restricted type certificate.;
- (16) points 21.A.95, 21.A.97 and 21.A.101 are replaced by the following:

‘21.A.95 Requirements for approval of a minor change

- (a) Minor changes to a type-certificate shall be classified and approved by:
 1. the Agency; or
 2. an approved design organisation within the scope of its privileges provided for in points (1) and (2) of point 21.A.263(c), as recorded in the terms of approval.
- (b) A minor change to a type-certificate shall only be approved:
 1. when it has been demonstrated that the change and areas affected by the change comply with the type-certification basis and the environmental protection requirements incorporated by reference in the type-certificate;
 2. in the case of a change affecting the operational suitability data, when it has been demonstrated that the necessary changes to the operational suitability data comply with the operational suitability data certification basis incorporated by reference in the type-certificate;
 3. when compliance with the type-certification basis that applies in accordance with point (1) has been declared and the justifications of compliance have been recorded in the compliance documents; and
 4. when no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

- (c) By derogation from point (1) in point (b), certification specifications which became applicable after those incorporated by reference in the type-certificate can be used for approval of a minor change, provided they do not affect the demonstration of compliance.
- (d) By derogation from point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), a minor change to an aircraft type-certificate may be approved before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are actually used.
- (e) The applicant shall submit to the Agency the substantiation data for the change and a statement that compliance has been demonstrated in accordance with point (b).
- (f) An approval of a minor change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.

21.A.97 Requirements for approval of a major change

- (a) Major changes to a type-certificate shall be classified and approved by:
 - 1. the Agency; or
 - 2. an approved design organisation within the scope of its privileges provided for in points (1) and (8) of point 21.A.263(c), as recorded in the terms of approval.
- (b) A major change to a type-certificate shall only be approved:
 - 1. when it has been demonstrated that the change and areas affected by the change comply with the type-certification basis and environmental protection requirements, as established by the Agency in accordance with point 21.A.101;
 - 2. in the case of a change affecting the operational suitability data, when it has been demonstrated that the necessary changes to the operational suitability data meet the operational suitability data certification basis, as established by the Agency in accordance with point 21.A.101; and
 - 3. when compliance with points (1) and (2) has been demonstrated in accordance with point 21.A.20, as applicable to the change.
- (c) By derogation from points (2) and (3) of point (b), at the applicant's request 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 operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are actually used.
- (d) An approval of a major change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.

21.A.101 Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate

- (a) A major change to a type-certificate and areas affected by the change shall comply with either the certification specifications applicable to the changed product on the date of the application for the change or certification specifications which became applicable after that date in accordance with point (f) below. The validity of the application shall be determined in accordance with point 21.A.93(c). In addition, the changed product shall comply with the environmental protection requirements designated by the Agency in accordance with point 21.B.85.
- (b) By derogation from point (a), an earlier amendment to a certification specification referred to in point (a) and to any other certification specification which is directly related may be used in any of the following situations, unless the earlier amendment became applicable before the date at which the corresponding certification specifications incorporated by reference in the type-certificate became applicable:
 - 1. a change that the Agency finds not to be significant. In determining whether a specific change is significant, the Agency shall consider the change in the context of all previous relevant design changes and all related revisions to the applicable certification specifications incorporated by reference in the type-certificate for the product. Changes meeting one of the following criteria shall automatically be 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 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) does not contribute materially to the level of safety of the changed product or is impractical.
- (c) By derogation from point (a), in the case of a change to an aircraft other than a rotorcraft of 2 722 kg (6 000 lb) or less maximum weight, or to a non-turbine rotorcraft of 1 361 kg (3 000 lb) or less maximum weight, the change and areas affected by the change shall comply 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 require that the change and areas affected by the change comply with an amendment to a certification specification of the type-certification basis incorporated by reference in the type-certificate and with any other certification specification which is directly related, unless the Agency also finds that compliance with that amendment does not contribute materially to the level of safety of the changed product or is impractical.
- (d) If the Agency finds that the certification specifications applicable on the date of the application for the change do not provide adequate standards with respect to the proposed change, the change and areas affected by the change shall also comply with any special conditions, and amendments to those special conditions, prescribed by the Agency in accordance with point 21.B.75, to provide a level of safety equivalent to that established by the certification specifications applicable on the date of the application for the change.
- (e) By derogation from points (a), (b) and (c), the change and areas affected by the change may comply with an alternative to a certification specification designated by the Agency if proposed by the applicant, provided that the Agency finds that the alternative provides a level of safety which is:
1. in the case of a type-certificate:
 - (i) equivalent to that of the certification specifications designated by the Agency under (a), (b) or (c) above; or
 - (ii) compliant with the essential requirements of Annex II to Regulation (EU) 2018/1139;
 2. in the case of a restricted type-certificate, adequate with regard to the intended use.
- (f) If an applicant chooses to comply with a certification specification set out in an amendment that becomes applicable after submitting the application for a change to a type-certificate, the change and areas affected by the change shall also comply with any other certification specification which 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 established in accordance with points (a)-(f).;
- (17) point 21.A.103 is deleted;
- (18) points 21.A.111 and 21.A.112A are 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. In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.

21.A.112A Eligibility

Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability in accordance with point 21.A.112B may apply for a supplemental type-certificate in accordance with the conditions laid down in this Subpart.;

- (19) point 21.A.112B is amended as follows:
- (a) point (a) is replaced by the following:
- ‘(a) An applicant for a supplemental type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.;

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

‘(c) By way of derogation from point (a), in the case of products referred to in point 21.A.14(c), an applicant may demonstrate its capability by obtaining the Agency’s acceptance of its certification programme established in accordance with point 21.A.93(b).’;

(20) point 21.A.113 is amended as follows:

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

‘(b) When applying for a supplemental type-certificate, the applicant shall:

- (i) include in the application the information required by point 21.A.93(b);
- (ii) specify whether the certification data has been or will be prepared completely by the applicant or on the basis of an arrangement with the owner of the type-certification data.’;

(b) the following point (c) is added:

‘(c) Point 21.A.93(c) applies to the requirements for the time limits of the application effectivity as well as the requirements related to the need to update the type-certification basis, operational suitability data certification basis and environmental protection requirements, when the change has not been approved or it is evident that it will not be approved within the time limit established.’;

(21) point 21.A.114 is deleted;

(22) point 21.A.115 is replaced by the following:

‘21.A.115 Requirements for approval of major changes in the form of a supplemental type-certificate

(a) Supplemental type certificates shall be issued by:

1. the Agency; or
2. an approved design organisation within the scope of its privileges provided for in points (1) and (9) of point 21.A.263(c), as recorded in the terms of approval.

(b) A supplemental type-certificate shall only be issued when:

1. the applicant has demonstrated its capability in accordance with point 21.A.112B;
2. it has been demonstrated that the change to a type-certificate and areas affected by the change comply with the type-certification basis and the environmental protection requirements, as established by the Agency in accordance with point 21.A.101;
3. in the case of a supplemental type-certificate affecting the operational suitability data, it has been demonstrated that the necessary changes to the operational suitability data meet the operational suitability data certification basis, as established by the Agency in accordance with point 21.A.101;
4. compliance with points (2) and (3) has been demonstrated in accordance with point 21.A.20, as applicable to the change; and
5. in case the applicant has specified that it provided certification data on the basis of an arrangement with the owner of the type-certification data in accordance with point 21.A.113(b):
 - (i) the type-certificate holder has indicated that it has no technical objection to the information submitted under point 21.A.93; and
 - (ii) the type-certificate holder has agreed to collaborate with the supplemental type-certificate holder to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with points 21.A.44 and 21.A.118A.

(c) By derogation from points (3) and (4) of point (b), at the applicant’s request included in the declaration referred to in point 21.A.20(d), the applicant is entitled to have a supplemental type-certificate for an aircraft issued before the applicant has demonstrated compliance with the operational suitability data certification basis, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

(d) A supplemental type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the related major change relates.’;

(23) in point 21.A.130, point (b) is replaced by the following:

‘(b) A statement of conformity shall include all of the below:

1. for each product, part or appliance, a statement that the product, part or appliance conforms to the approved design data and is in condition for safe operation;
2. for each aircraft, a statement that the aircraft has been ground- and flight-checked in accordance with point 21.A.127(a);
3. for each engine, or variable pitch propeller, a statement that the engine or variable pitch propeller has been subjected by the manufacturer to a final functional test in accordance with point 21.A.128;
4. additionally, in the case of environmental requirements:
 - (i) a statement that the completed engine is in compliance with the applicable engine exhaust emissions requirements on the date of manufacture of the engine, and;
 - (ii) a statement that the completed aeroplane is in compliance with the applicable CO₂ emissions requirements on the date its first certificate of airworthiness is issued.’;

(24) in point 21.A.145, points (b) and (c) are replaced by the following:

‘(b) with regard to all necessary airworthiness and environmental data:

1. the production organisation is in receipt of such data from the Agency, and from the holder of, or applicant for, the type-certificate, restricted type-certificate or design approval, including any exemption granted against the CO₂ production cut-off requirements, to determine conformity with the applicable design data;
2. the production organisation has established a procedure to ensure that airworthiness and environmental data are correctly incorporated in its production data and,
3. such data are kept up to date and made available to all personnel who need access to such data to perform their duties.

(c) with regard to management and staff:

1. a manager has been nominated by the production organisation, and is accountable to the competent authority. His or her responsibilities within the organisation shall consist of ensuring that all production is performed to the required standards and that the production organisation is continuously in compliance with the data and procedures identified in the exposition referred to in point 21.A.143;
2. a person or group of persons have been nominated by the production organisation to ensure that the organisation is in compliance with the requirements of this Annex (Part 21), and are identified, together with the extent of their authority. Such person(s) shall act under the direct authority of the accountable manager referred to in point (1). The person(s) nominated shall be able to show the appropriate knowledge, background and experience to discharge their responsibilities;
3. staff at all levels have been given appropriate authority to be able to discharge their allocated responsibilities and that there is full and effective coordination within the production organisation in respect of airworthiness and environmental data matters.’;

(25) in point 21.A.147, point (a) is replaced by the following:

‘(a) After the issue of a production organisation approval, each change to the approved production organisation that is significant to the showing of conformity or to the airworthiness and environmental characteristics of the product, part or appliance, particularly changes to the quality system, shall be approved by the competent authority. An application for approval shall be submitted in writing to the competent authority and the organisation shall demonstrate to the competent authority, before implementing the change, that it complies with this Subpart.’;

(26) in point 21.A.174, point (b) is replaced by the following:

‘(b) Each application for a certificate of airworthiness or restricted certificate of airworthiness shall include:

1. the class of airworthiness certificate applied for;

2. with regard to new aircraft:
 - (i) a statement of conformity:
 - issued under point 21.A.163(b); or
 - issued under point 21.A.130 and validated by the competent authority; or
 - for an imported aircraft, a statement signed by the exporting authority that the aircraft conforms to a design approved by the Agency;
 - (ii) a weight and balance report with a loading schedule and;
 - (iii) the flight manual, when required by the applicable certification specifications for the particular aircraft.
3. with regard to used aircraft:
 - (i) originating from a Member State, an airworthiness review certificate issued in accordance with Part-M;
 - (ii) originating from a non-Member State:
 - a statement by the competent authority of the State where the aircraft is, or was, registered, reflecting the airworthiness status of the aircraft on its register at the time of transfer;
 - a weight and balance report with a loading schedule;
 - the flight manual when such material is required by the applicable airworthiness code for the particular aircraft;
 - historical records to establish the production, modification, and maintenance standard of the aircraft, including all limitations associated with a restricted certificate of airworthiness under point 21.B.327;
 - a recommendation for the issue of a certificate of airworthiness or restricted certificate of airworthiness and an airworthiness review certificate following an airworthiness review in accordance with Part-M; and
 - the date on which the first certificate of airworthiness was issued and, if the standards of Annex 16 Volume III apply, the CO₂ metric value data.;

(27) point 21.A.231 is replaced by the following:

‘21.A.231 Scope

This Subpart establishes the procedure for the approval of design organisations and rules governing the rights and obligations of applicants for, and holders of, such approvals. In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.’

(28) 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 with regard to the airworthiness, operational suitability and environmental characteristics of the products. For design organisation approvals covering type-certification or European Technical Standard Order (ETSO) authorisation for auxiliary power units (APUs), the terms of approval shall contain in addition the list of products or APUs. Those terms shall be issued as part of a design organisation approval.’

(29) point 21.A.258 is amended as follows:

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

- ‘(a) When, during the investigations referred to in points 21.A.257 and 21.B.100, objective evidence is found demonstrating non-compliance of the holder of a design organisation approval with the applicable requirements of this Annex, the finding shall be classified as follows:
1. a “level 1” finding is any non-compliance with the requirements of this Annex that may lead to uncontrolled non-compliances with applicable requirements and affect the safety of the aircraft;
 2. a “level 2” finding is any non-compliance with the requirements of this Annex that is not classified as a “level 1” finding.’;

(b) points (c) and (d) are replaced by the following:

‘(c) After receipt of notification of findings under the applicable administrative procedures established by the Agency:

1. in the case of a “level 1” finding, the holder of a design organisation approval shall demonstrate to the satisfaction of the Agency that it has taken adequate corrective action within a period of no more than 21 working days after written confirmation of the finding;
2. in the case of a “level 2” findings, the holder of a design organisation approval shall demonstrate to the satisfaction of the Agency that it has taken adequate corrective action within a time period set by the Agency which is appropriate to the nature of the finding and is initially no longer than three months. The Agency may extend that initial time period where it considers that the nature of the finding allows such extension and where the applicant has submitted a corrective action plan which the Agency finds satisfactory; and
3. a “level 3” finding shall not require immediate action by the holder of a design organisation approval.

(d) In cases of “level 1” or “level 2” findings, the design organisation approval may be subject to a partial or full suspension or revocation under the applicable administrative procedures established by the Agency. In that case, the holder of a design organisation approval shall provide confirmation of receipt of the notice of suspension or revocation of the design organisation approval in a timely manner.’;

(30) point 21.A.263 is replaced by the following:

‘21.A.263 Privileges

(a) (Reserved)

(b) (Reserved)

(c) A holder of a design organisation approval shall be entitled, within the scope of its terms of approval, as established by the Agency, and under the relevant procedures of the design assurance system:

1. to classify changes to a type-certificate or to a supplemental type-certificate and repair designs as “major” or “minor”;
2. to approve minor changes to a type-certificate or to a supplemental type-certificate and minor repair designs;
3. (Reserved);
4. (Reserved);
5. to approve certain major repair designs under Subpart M to products or auxiliary power units (APUs);
6. to approve for certain aircraft the flight conditions under which a permit to fly can be issued in accordance with point 21.A.710(a)(2), except for permits to fly to be issued for the purpose of point 21.A.701(a)(15);
7. to issue a permit to fly in accordance with point 21.A.711(b) for an aircraft it has designed or modified, or for which it has approved, in accordance with point 21.A.263(c)(6), the flight conditions under which the permit to fly can be issued, and where the holder of a design organisation approval itself:
 - (i) controls the configuration of the aircraft, and
 - (ii) attests conformity with the design conditions approved for the flight;
8. to approve certain major changes to a type-certificate under Subpart D; and
9. to issue certain supplemental type-certificates under Subpart E and approve certain major changes to those certificates.’;

(31) point 21.A.265 is replaced by the following:

‘21.A.265 Obligations of the holder

The holder of a design organisation approval shall, within the scope of its terms of approval, as established by the Agency:

- (a) maintain the handbook required under point 21.A.243 in conformity with the design assurance system;
- (b) ensure that this handbook or the relevant procedures included by cross-reference are used as a basic working document within the organisation;

- (c) determine that the design of products, or changes or repairs thereto comply with the applicable specifications and requirements and have no unsafe features;
 - (d) provide the Agency with statements and associated documentation confirming compliance with point (c), except for approval processes carried out in accordance with point 21.A.263(c);
 - (e) provide to the Agency data and information related to the actions required under point 21.A.3B;
 - (f) determine, in accordance with point 21.A.263(c)(6), the flight conditions under which a permit to fly can be issued;
 - (g) establish, in accordance with point 21.A.263(c)(7), compliance with points (b) and (e) of point 21.A.711 before issuing a permit to fly to an aircraft;
 - (h) designate data and information issued under the authority of the approved design organisation within the scope of its terms of approval as established by the Agency with the following statement: "The technical content of this document is approved under the authority of the DOA ref. EASA. 21J.[XXXX]";
- (32) point 21.A.431A is amended as follows:
- (a) point (a) is replaced by the following:

'(a) This Subpart establishes the procedure for the approval of a repair design of a product, part or appliance and establishes the rights and obligations of the applicants for, and holders of, those approvals.'
 - (b) points (c) and (d) are replaced by the following:

'(c) A "repair" means the elimination of damage and/or restoration to an airworthy condition following the initial release to service by the manufacturer of any product, part or appliance.

(d) The elimination of damage by replacement of parts or appliances without the necessity for design activity shall be considered as a maintenance task and shall therefore require no approval under this Annex.'
 - (c) the following point (f) is added:

'(f) In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.'
- (33) point 21.A.432B is amended as follows:
- (a) point (a) is replaced by the following:

'(a) An applicant for approval of a major repair design shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.'
 - (b) point (c) is replaced by the following:

'(c) By way of derogation from point (a), in the case of products referred to in point 21.A.14(c), an applicant may demonstrate its capability by obtaining the Agency's acceptance of its certification programme established in accordance with point 21.A.432C(b).'
- (34) the following point 21.A.432C is inserted:

'21.A.432C Application for a repair design approval

- (a) An application for a repair design approval shall be made in a form and manner established by the Agency.
- (b) An application for a major repair design approval shall include, or be supplemented after the initial application, a certification programme containing:
 1. a description of the damage and repair design identifying the configuration of the type design upon which the repair is made;
 2. an identification of all areas of the type design and the approved manuals that are changed or affected by the repair design;
 3. an identification of any reinvestigations necessary to demonstrate compliance of the repair design and areas affected by the repair design with the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation;
 4. any proposed amendments to the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation;

5. a proposal for a breakdown of the certification programme into meaningful groups of compliance demonstration activities and data, including the means and process proposed to be followed to demonstrate compliance with point 21.A.433(a)(1) and references to related compliance documents;
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 and the potential impact of that non-compliance on product safety. The proposed assessment shall take into account at least the elements set out in subpoints (1)-(4) of point 21.B.100(a). Based on this assessment, the application shall include a proposal for the Agency's involvement in the verification of the compliance demonstration activities and data; and
7. the specification whether the certification data is prepared completely by the applicant or on the basis of an arrangement with the owner of the type-certification data.;

(35) points 21.A.433 and 21.A.435 are replaced by the following:

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

(a) A repair design shall only be approved:

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 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 that applies in accordance with point (a)(1) has been declared and the justifications of compliance have been recorded in the compliance documents;
3. when no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested; and
4. where the applicant has specified that it provided certification data on the basis of an arrangement with the owner of the type-certification data in accordance with point 21.A.432C(b)(7):
 - (i) when the holder has indicated that it has no technical objection to the information submitted under point (a)(2); and
 - (ii) when the holder has agreed to collaborate with the repair design approval holder to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with point 21.A.451.

(b) The applicant shall submit to the Agency the declaration referred to in point (a)(2) and, on request by the Agency, all necessary substantiation data.

21.A.435 Classification and approval of repair designs

- (a) A repair design shall be classified as either “major” or “minor” in accordance with the criteria set out in point 21.A.91 for a change to the type-certificate.
- (b) A repair design shall be classified and approved by:
 1. the Agency; or
 2. an approved design organisation within the scope of its privileges provided for in points (1), (2) and (5) of point 21.A.263(c), as recorded in the terms of approval.;

(36) point 21.A.437 is deleted;

(37) points 21.A.604, 21.A.605 and 21.A.606 are replaced by the following:

‘21.A.604 ETSO authorisation for an auxiliary power unit (APU)

With regard to an ETSO authorisation for an APU:

- (a) by way of derogation from points 21.A.603, 21.A.610 and 21.A.615, the following points shall apply: points 21.A.15, 21.A.20, 21.A.21, 21.A.31, 21.A.33, 21.A.44, 21.B.75 and 21.B.80. However, an ETSO authorisation shall be issued in accordance with point 21.A.606 instead of a type-certificate;

- (b) by way of derogation from point 21.A.611, the requirements of Subpart D shall apply to the approval of design changes by the APU ETSO authorisation holder and the requirements of Subpart E shall apply to the approval of design changes by other applicants. Where the requirements of Subpart E apply, a separate ETSO authorisation shall be issued instead of a supplemental type certificate; and
- (c) the requirements of Subpart M shall apply to the approval of repair designs.

21.A.605 Data requirements

- (a) The applicant shall submit to the Agency the following documents:
 1. a certification programme for the ETSO authorisation, setting out the means to demonstrate compliance with point 21.A.606(b);
 2. a statement of compliance certifying that the applicant has met the requirements of this Subpart;
 3. a declaration of design and performance (DDP), stating that the applicant has demonstrated that the article complies with the applicable ETSO in accordance with the certification programme;
 4. a copy of the technical data required in the applicable ETSO;
 5. the exposition, or a reference to the exposition, referred to in point 21.A.143 for the purpose of obtaining an appropriate production organisation approval under Subpart G or the manual, or a reference to the manual, referred to in point 21.A.125A(b) for the purpose of manufacturing under Subpart F without production organisation approval;
 6. for an APU, the handbook, or a reference to the handbook, referred to in point 21.A.243 for the purpose of obtaining an appropriate design organisation approval under Subpart J;
 7. for all other articles, the procedures, or a reference to the procedures, referred to in point 21.A.602B(b)(2);
- (b) The applicant shall report to the Agency any difficulty or event encountered during the approval process that may significantly impact the ETSO authorisation.

21.A.606 Requirements for the issuance of an ETSO authorisation

In order to be issued an ETSO authorisation, the applicant shall:

- (a) demonstrate its capability in accordance with point 21.A.602B;
 - (b) demonstrate that the article complies with the technical conditions of the applicable ETSO or with deviations therefrom approved in accordance with point 21.A.610, if any;
 - (c) comply with the requirements of this Subpart; and
 - (d) declare that no feature or characteristic has been identified that may make the article unsafe for the uses for which certification is requested.;
- (38) in point 21.A.701, point (16) is added:
- ‘16. flying an aircraft for troubleshooting purposes or to check the functioning of one or more systems, parts or appliances after maintenance.’;
- (39) in point 21.B.5, point (a) is replaced by the following:
- ‘(a) This Section establishes the procedure for the competent authority, when exercising its tasks and responsibilities concerned with the issuance, maintenance, amendment, suspension and revocation of certificates, approvals and authorisations referred to in this Annex I.’
- (40) Subpart B of Section B is replaced by the following:

‘SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

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, operational suitability data and environmental protection, that competent authorities, organisations and personnel may use to demonstrate compliance of products, parts and appliances with the relevant essential requirements set out in Annexes II, IV and V to that Regulation, as well as with those for environmental protection set out in Article 9(2) and Annex III of that Regulation. Such specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which certificates are to be issued, amended or supplemented.

21.B.75 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;
 2. the intended use of the product is unconventional; or
 3. experience from other similar products in service or products having similar design features or newly identified hazards have shown that unsafe conditions may develop.
- (b) Special conditions contain such safety standards as the Agency finds necessary in order to establish a level of safety equivalent to that of the applicable certification specifications.

21.B.80 Type-certification basis for a type-certificate or restricted type-certificate

The Agency shall establish the type certification basis and notify it to the applicant for a type-certificate or restricted type-certificate. The type certification basis shall consist of:

- (a) the certification specifications for airworthiness designated by the Agency from those applicable to the product at the date of application for that certificate, unless:
1. the applicant chooses to comply, or is required to comply in accordance with point 21.A.15(f), with certification specifications which became applicable after the date of the application; If an applicant chooses to comply with a certification specification which became applicable after the date of the application, the Agency shall include in the type-certification basis any other certification specification that is directly related; or
 2. the Agency accepts any alternative to a designated certification specification that cannot be complied with, for which compensating factors have been found that provide an equivalent level of safety; or
 3. the Agency accepts or prescribes other means that:
 - (i) in the case of a type-certificate, demonstrate compliance with the essential requirements of Annex II to Regulation (EU) 2018/1139; or
 - (ii) in the case of a restricted type-certificate, provide a level of safety adequate with regard to the intended use; and
- (b) any special condition prescribed by the Agency in accordance with point 21.B.75(a).

21.B.82 Operational suitability data certification basis for an aircraft type-certificate or restricted type-certificate

The Agency shall establish the operational suitability data certification basis and notify it to the applicant for an aircraft type-certificate or restricted type-certificate. The operational suitability data certification basis shall consist of:

- (a) the certification specifications for operational suitability data designated by the Agency out of those applicable to the aircraft at the date of the application or at the date of the application supplement for operational suitability data, whichever date is later, unless:
1. the applicant chooses to comply, or in accordance with point 21.A.15(f) is required to comply with certification specifications which became applicable after the date of the application; If an applicant chooses to comply with a certification specification which became applicable after the date of the application, the Agency shall include in the type-certification basis any other certification specification that is directly related; or
 2. the Agency accepts or prescribes alternative means to demonstrate compliance with the relevant essential requirements of Annexes II, IV and V to Regulation (EU) 2018/1139.
- (b) any special condition prescribed by the Agency in accordance with point 21.B.75(a).

21.B.85 Designation of applicable environmental protection requirements and certification specifications for a type-certificate or restricted type-certificate

- (a) The Agency shall designate and notify to the applicant for a type-certificate or restricted type-certificate for an aircraft, for a supplemental type-certificate or for a major change to a type-certificate or to a supplemental type-certificate, the applicable noise requirements established in Annex 16 to the Chicago Convention, Volume I, Part II, Chapter 1 and:
1. for subsonic jet aeroplanes, in Chapters 2, 3, 4 and 14;
 2. for propeller-driven aeroplanes in Chapters 3, 4, 5, 6, 10, and 14;
 3. for helicopters, in Chapters 8 and 11;
 4. for supersonic aeroplanes, in Chapter 12; and
 5. for tilt rotors, in Chapter 13.
- (b) The Agency shall designate and notify to the applicant referred to in point (a) the applicable emission requirements for preventions of intentional fuel venting for aircraft established in Annex 16 to the Chicago Convention, Volume II, Part II, Chapter 1 and 2.
- (c) The Agency shall designate and notify to the applicant referred to in point (a) the applicable smoke, gaseous and particulate matter engine emission requirements established in Annex 16 to the Chicago Convention, Volume II, Part III, Chapter 1 and
1. for smoke and gaseous emissions of turbojet and turbofan engines intended for propulsion only at subsonic speeds, in Chapter 2;
 2. for smoke and gaseous emissions of turbojet and turbofan engines intended for propulsion at supersonic speeds, in Chapter 3; and
 3. for particulate matter emissions of turbojet and turbofan engines intended for propulsion only at subsonic speeds, in Chapter 4.
- (d) The Agency shall designate and notify to the applicant referred to in point (a) the applicable aeroplane CO₂ emission requirements established in Annex 16 to the Chicago Convention, Volume III, Part II, Chapter 1 and
1. for subsonic jet aeroplanes, in Chapter 2; and
 2. for subsonic propeller-driven aeroplanes, in Chapter 2.

21.B.100 Level of involvement

- (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 APU. 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 environmental protection requirements; and
 - the potential impact of that non-compliance on product safety or environmental protection,
- and consider at least the following elements:
1. novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;
 2. complexity of the design and/or demonstration of compliance;
 3. criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and
 4. performance and experience of the design organisation of the applicant in the domain concerned.

- (b) For the approval of a minor repair design, minor change or ETSO authorisation other than for APU, the Agency shall determine its involvement at the level of the entire certification project, taking into account any novel or unusual features, complexity of the design and/or demonstration of compliance, criticality of the design or technology, as well as the performance and experience of the applicant's design organisation.
- (c) The Agency shall notify its level of involvement to the applicant and it shall update its level of involvement when this is warranted by information which has an appreciable impact on the risk previously assessed pursuant to point (a) or (b). The Agency shall notify the applicant about the change in the level of involvement.

21.B.103 Issuance of a type-certificate or restricted type-certificate

- (a) The Agency shall issue an aircraft, engine or propeller type-certificate or an aircraft restricted type-certificate, provided that:
 - 1. the applicant has complied with point 21.A.21;
 - 2. the Agency, through verifications of the demonstration of compliance in accordance with its involvement determined pursuant to point 21.B.100, has not found any non-compliance with the type-certification basis, the operational suitability data certification basis where applicable in accordance with point 21.B.82, and the environmental protection requirements; and
 - 3. no feature or characteristic has been identified that may make the product unsafe for the uses for which the certification is requested.
- (b) By derogation from point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may issue an aircraft type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.'

(41) Subpart D of Section B 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 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.

21.B.107 Issuance of an approval of a change to a type-certificate

- (a) The Agency shall issue an approval of a change to a type-certificate provided that:
 - 1. the applicant for an approval has complied with:
 - (i) point 21.A.95 for a minor change; or
 - (ii) point 21.A.97 for a major change;
 - 2. the Agency, through its verification of the demonstration of compliance in accordance with the level of its involvement determined pursuant to point (a) or (b) of point 21.B.100 has not found any non-compliance with the type-certification basis, operational suitability data certification basis where applicable in accordance with point 21.B.82, and environmental protection requirements; and
 - 3. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.
- (b) In the case of a change affecting the operational suitability data, by derogation from points (1) and (2) of point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may approve a change to an aircraft type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

- (c) The approval of the changes to the operational suitability data shall be included in the approval of the change to the type-certificate.
- (d) The approval of a change to a type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the change relates.;

(42) Subpart E of Section B is replaced by the following:

‘In this Subpart, references to type-certificates include type-certificates and restricted type-certificates.

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 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.

21.B.111 Issuance of a supplemental type-certificate

(a) The Agency shall issue a supplemental type-certificate, provided that:

1. the applicant has complied with point 21.A.115(b);
2. 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, operational suitability data certification basis where applicable in accordance with point 21.B.82, and environmental protection requirements; and
3. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.

(b) In the case of a supplemental type-certificate affecting the operational suitability data, by derogation from points (1) and (2) of point (a), at the applicant's request included in the declaration referred to in point 21.A.20(d), the Agency may issue a supplemental type-certificate before compliance with the operational suitability data certification basis has been demonstrated, provided that the applicant demonstrates such compliance before the date at which those data are to be actually used.

(c) The approval of the changes to the operational suitability data shall be included in the supplemental type-certificate.

(d) The supplemental type-certificate shall be limited to the specific configuration(s) in the type-certificate to which the related major change relates.;

(43) Point 21.B.326 is replaced by the following:

‘21.B.326 Certificate of airworthiness

The competent authority of the Member State of registry shall issue a certificate of airworthiness for:

(a) new aircraft:

1. upon presentation of the documentation required by point 21.A.174(b)(2);
2. where the competent authority of the Member State of registry is satisfied that the aircraft conforms to an approved design and is in a condition for safe operation; this may include inspections by the competent authority of the Member State of registry; and
3. where the competent authority of the Member State of registry is satisfied that the aircraft is in compliance with the applicable CO₂ emissions requirements on the date on which the certificate of airworthiness is first issued.

(b) used aircraft:

1. upon presentation of the documentation required by point 21.A.174(b)(3) demonstrating that:
 - (i) the aircraft conforms to a type design approved under a type-certificate and any supplemental type-certificate, change or repair approved in accordance with this Annex I (Part 21) and;
 - (ii) the applicable airworthiness directives have been complied with and;

- (iii) the aircraft has been inspected in accordance with the applicable provisions of Annex I (Part-M) to Regulation (EC) No 2042/2003 and;
 - (iv) the aircraft was in compliance with the applicable CO₂ emissions requirements on the date on which the certificate of airworthiness was first issued;
- 2. where the competent authority of the Member State of registry is satisfied that the aircraft conforms to an approved design and is in a condition for safe operation; this may include inspections by the competent authority of the Member State of registry and;
 - 3. where the competent authority of the Member State of registry is satisfied that the aircraft was in compliance with the applicable CO₂ emissions requirements on the date on which the certificate of airworthiness was first issued.'

(44) Subpart M of Section B is replaced by the following:

'21.B.450 Type-certification basis and environmental protection requirements for a repair design approval

The Agency shall designate any amendments to the type-certification basis incorporated by reference in, as applicable, either the type-certificate, the supplemental type-certificate or the APU ETSO authorisation, which the Agency considers necessary for maintaining a level of safety equal to that previously established and notify them to the applicant for a repair design.

21.B.453 Issuance of a repair design approval

- (a) The Agency shall issue an approval of a major repair design, provided that:
 - 1. the applicant has demonstrated its capability in accordance with point 21.A.432B;
 - 2. the applicant has complied with point 21.A.433;
 - 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 environmental protection requirements; and
 - 4. no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested.
- (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 verifications 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 environmental protection requirements.';

(45) Subpart O of Section B is replaced by the following:

'21.B.480 Issuance of an ETSO authorisation

The Agency shall issue an ETSO authorisation, provided that:

- (a) the applicant has complied with point 21.A.606;
 - (b) the Agency, through its verifications 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 technical conditions of the applicable ETSO or with deviations therefrom approved in accordance with point 21.A.610, if any; and
 - (c) no feature or characteristic has been identified that may make the article unsafe for the uses for which certification is requested.'
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COMMISSION IMPLEMENTING REGULATION (EU) 2019/898**of 29 May 2019****concerning the authorisation of the preparation of eugenol as a feed additive for chickens for fattening (holder of authorisation Lidervet SL)****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of eugenol. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of the preparation eugenol as a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 21 October 2015 ⁽²⁾ and 4 July 2017 ⁽³⁾ that, under the proposed conditions of use, eugenol does not have an adverse effect on animal health, human health or the environment. The Authority concluded that the additive is considered efficacious in improving the growth of chickens for fattening. The Authority did not consider that there was a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of eugenol shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of eugenol should be authorised as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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*.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2015;13(11):4273.

⁽³⁾ EFSA Journal 2017;15(7):4931.

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

Done at Brussels, 29 May 2019.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of additive/kg of complete feedstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of zootechnical performance).									
4d18	Lidervet SL	Preparation of Eugenol	<i>Additive composition</i> Preparation of: — eugenol 5 %; — glyceryl polyethyleneglycol ricinoleate 55-56 %; — silica amorphous 33 %; — poly(methacrylic acid-co-ethyl acrylate) 6 %. Granulated form <i>Characterisation of active substance</i> Eugenol (2-methoxy-4-(2-propenyl)phenol, 4-allyl-2-methoxyphenol, 4-allylguaiacol.) (99,5 %); CAS no 97-53-0 C₁₀H₁₂O₂ <i>Analytical method ⁽¹⁾</i> For the quantification of eugenol in the feed additive and feeding-stuffs: — Gas Chromatography coupled to a Flame Ionization Detector (GC-FID)	Chickens for fattening	—	100	100	1. In the directions for use of the additive and premixture, the storage conditions and stability to heating treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment. 3. The mixing with other sources of eugenol is not permitted.	23 June 2029

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2019/899

of 29 May 2019

concerning the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, horses and pigs for fattening and repealing Regulations (EC) No 1447/2006, (EC) No 188/2007, (EC) No 232/2009, (EC) No 186/2007 and (EC) No 209/2008 (holder of authorisation S.I. Lesaffre)

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) *Saccharomyces cerevisiae* NCYC Sc 47 was authorised for 10 years as a feed additive for lambs for fattening by Commission Regulation (EC) No 1447/2006 ⁽²⁾, for horses by Commission Regulation (EC) No 186/2007 ⁽³⁾, for dairy goats and dairy sheep by Commission Regulation (EC) No 188/2007 ⁽⁴⁾, for pigs for fattening by Commission Regulation (EC) No 209/2008 ⁽⁵⁾ and for dairy buffaloes by Commission Regulation (EC) No 232/2009 ⁽⁶⁾.
- (3) In accordance with Article 14 of Regulation (EC) No 1831/2003, applications were submitted by the holder of those authorisations for the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-4407 (formerly NCYC Sc 47) as a feed additive for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, pigs for fattening and horses requesting that additive to be classified in the additive category 'zootechnical additives'. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 June 2018 ⁽⁷⁾ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation.
- (5) The assessment of *Saccharomyces cerevisiae* CNCM I-4407 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-4407 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 1447/2006, (EC) No 186/2007, (EC) No 188/2007, (EC) No 209/2008 and (EC) No 232/2009 should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 1447/2006 of 29 September 2006 concerning the authorisation of a new use of *Saccharomyces cerevisiae* (Biosaf SC 47) as a feed additive (OJ L 271, 30.9.2006, p. 28).

⁽³⁾ Commission Regulation (EC) No 186/2007 of 21 February 2007 concerning the authorisation of a new use of *Saccharomyces cerevisiae* (Biosaf SC 47) as a feed additive (OJ L 63, 1.3.2007, p. 6).

⁽⁴⁾ Commission Regulation (EC) No 188/2007 of 23 February 2007 concerning the authorisation of a new use of *Saccharomyces cerevisiae* (Biosaf SC 47) as a feed additive (OJ L 57, 24.2.2007, p. 3).

⁽⁵⁾ Commission Regulation (EC) No 209/2008 of 6 March 2008 concerning the authorisation of a new use of *Saccharomyces cerevisiae* (Biosaf SC 47) as a feed additive (OJ L 63, 7.3.2008, p. 3).

⁽⁶⁾ Commission Regulation (EC) No 232/2009 of 19 March 2009 concerning the authorisation of a new use of *Saccharomyces cerevisiae* NCYC Sc47 as a feed additive for dairy buffaloes (holder of the authorisation Société Industrielle Lesaffre) (OJ L 74, 20.3.2009, p. 14).

⁽⁷⁾ EFSA Journal 2018;16(7):5339.

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' when it is used for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes and pigs for fattening; and to the functional group 'digestibility enhancers' when it is used for horses, is renewed subject to the conditions laid down in that Annex.

Article 2

Saccharomyces cerevisiae NCYC Sc47as feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 1447/2006, (EC) No 186/2007, (EC) No 188/2007, (EC) No 209/2008 and (EC) No 232/2009, and premixtures and compound feed containing it, labelled in accordance with those Regulations before the entry into force of this Regulation, may be continued to be placed on the market until the existing stocks are exhausted.

Article 3

Regulations (EC) No 1447/2006, (EC) No 186/2007, (EC) No 188/2007, (EC) No 209/2008 and (EC) No 232/2009 are repealed.

Article 4

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

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

Done at Brussels, 29 May 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1702	S.I. Lesaffre	Saccharomyces cerevisiae CNCM I-4407	Additive composition: Preparation of Saccharomyces cerevisiae CNCM I-4407 with a minimum concentration of 5 × 10 ⁹ CFU/g. Solid form Characterisation of the active substance: Viable dried cells of Saccharomyces cerevisiae CNCM I-4407 Analytical method ⁽¹⁾ Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN 15789:2009). Identification: polymerase chain reaction (PCR) method CEN/TS 15790:2008.	Lambs for fattening	—	1,4 × 10 ⁹	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Recommended doses (CFU/head/day) for: — dairy goats: 3 × 10 ⁹ — dairy sheep: 2 × 10 ⁹ 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and breathing protection.	23 June 2029
				Dairy goats and dairy sheep		7 × 10 ⁸			
				Pigs for fattening		1,25 × 10 ⁹			
				Dairy buffaloes		5 × 10 ⁸			

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers

4b1702	S.I. Lesaffre	<i>Saccharomyces cerevisiae</i> CNCM I-4407	<i>Additive composition:</i> Preparation of <i>Saccharomyces cerevisiae</i> CNCM I-4407 with a minimum concentration of 5×10^9 CFU/g. Solid form <i>Characterisation of the active substance:</i> Viable dried cells of <i>Saccharomyces cerevisiae</i> CNCM I-4407 <i>Analytical method</i> ⁽¹⁾ Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN 15789:2009). Identification: polymerase chain reaction (PCR) method CEN/TS 15790:2008.	Horses	—	8×10^8	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Recommended doses (CFU/head/day) for: — horses: $1,25 \times 10^{10} - 6 \times 10^{10}$ 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and breathing protection.	23 June 2029
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⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2019/900**of 29 May 2019****concerning the authorisation of 8-mercapto-p-menthan-3-one and p-menth-1-ene-8-thiol as feed additives for all animal species****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) 8-mercapto-p-menthan-3-one and p-menth-1-ene-8-thiol were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those products were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the 8-mercapto-p-menthan-3-one and p-menth-1-ene-8-thiol as feed additives for all animal species. The applicant requested those additives to be classified in the additive category 'sensory additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 November 2018 ⁽³⁾ that, under the proposed conditions of use in feed 8-mercapto-p-menthan-3-one and p-menth-1-ene-8-thiol do not have adverse effects on animal health, consumer safety or the environment. It also concluded that both compounds are irritant to the respiratory tract and no conclusions can be drawn for skin sensitisation potential. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular, as regards the users of the additive. The Authority further concluded that since the two substances are used in food and their function in feed is the same as that in food, no further demonstration of efficacy in feed is necessary.
- (5) Restrictions and conditions should be provided for to allow for a better control. For 8-mercapto-p-menthan-3-one and p-menth-1-ene-8-thiol recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures and in the labelling compound feeds and feed materials.
- (6) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2019;17(1):5530.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Transitional Measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 23 December 2019 in accordance with the rules applicable before 23 June 2019 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 23 June 2020 in accordance with the rules applicable before 23 June 2019 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 23 June 2021 in accordance with the rules applicable before 23 June 2019 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

Entry into Force

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

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

Done at Brussels, 29 May 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b12038	—	8-mercapto-p-menthan-3-one	<i>Additive composition</i> 8-mercapto-p-menthan-3-one <i>Characterisation of the active substance</i> 8-mercapto-p-menthan-3-one Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₁₀ H ₁₈ OS CAS number 38462-22-5 FLAVIS 12.038 <i>Method of analysis</i> ⁽¹⁾ For the determination of 8-mercapto-p-menthan-3-one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 mg/kg’ 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg.	23 June 2029

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
								5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	
2b12085	—	p-menth-1-ene-8-thiol	<i>Additive composition</i> p-menth-1-ene-8-thiol <i>Characterisation of the active substance</i> p-menth-1-ene-8-thiol Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₁₈ OS CAS number 71159-90-5 FLAVIS 12.085	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 mg/kg’	23 June 2029

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of p-menth-1-ene-8-thiol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection safety glasses and gloves.	

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2019/901

of 29 May 2019

concerning the authorisation of riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) (sources of vitamin B₂) as feed additives for all animal species.

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) were authorised as sources of vitamin B₂ without a time limit as feed additives for all animal species in accordance with Directive 70/524/EEC. Those additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, two applications were submitted for the re-evaluation of riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) for all animal species, requesting those additives to be classified in the additive category 'nutritional additives'. One application concerns riboflavin produced by *Ashbya gossypii* (DSM 23096) and the other application concerns riboflavin and riboflavin 5'-phosphate ester monosodium salt, both produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984). Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) In accordance with Article 7 of Regulation (EC) No 1831/2003, one of the two applications also requested the authorisation of riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) as feed additives for all animal species for use in water for drinking. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003 for the use in water for drinking.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 3 December 2015 ⁽³⁾ and 13 June 2018 ⁽⁴⁾ that, under the proposed conditions of use, riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) do not have adverse effects on animal health, consumer safety or the environment. It also concluded that the additives containing riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) are not irritant to skin and eyes. In the absence of data, the Authority cannot conclude on skin sensitisation. Riboflavin is a recognised as photosensitiser, which may elicit skin and eye photoallergic reactions. Workers might be exposed to a respirable dust when handling riboflavin and riboflavin 5'-phosphate sodium salt; in the absence of data on inhalation toxicity, the Authority cannot conclude on a possible risk by inhalation. Therefore, the Commission

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ EFSA Journal 2016;14(1):4349.⁽⁴⁾ EFSA Journal 2018;16(7):5337.

consider that appropriate protective measures should be taken to prevent effects on human health, in particular as regards the users of the additive. The Authority further concluded that riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) are effective sources of vitamin B₂ in covering the animal's nutritional requirements. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis in feed and, where applicable, in water, submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (6) The assessment of riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied for the use in feed and for riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) also for the use in water for drinking. Accordingly, the use of those additives should be authorised as specified in the Annex to this Regulation.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional Measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 23 June 2019 in accordance with the rules applicable before 23 June 2019 may continue to be placed on the market and used until 23 December 2019.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 23 June 2020 in accordance with the rules applicable before 23 June 2019 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 23 June 2021 in accordance with the rules applicable before 23 June 2019 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

Entry into Force

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

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

Done at Brussels, 29 May 2019.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect.									
3a825i	—	'Riboflavin' or 'Vitamin B ₂ '	<i>Additive composition</i> Riboflavin produced by <i>Ashbya gossypii</i> DSM 23096 <i>Characterisation of the active substance</i> Riboflavin C ₁₇ H ₂₀ N ₄ O ₆ CAS number: 83-88-5 Riboflavin solid form produced by <i>Ashbya gossypii</i> DSM 23096 Purity criteria: min. 80 % of riboflavin <i>Method of analysis</i> ⁽¹⁾ For the determination of Riboflavin in the feed additive: spectrophotometry at 444 nm For the determination of Riboflavin in premixtures: high-Performance Liquid Chromatography coupled to UV detector, HPLC-UV (VDLUFA Bd.III, 13.9.1) For the determination of Riboflavin in feedingstuffs: high Performance Liquid Chromatography with Fluorescence detection, HPLC-FL (EN 14152)	All animal species	—	—	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	23 June 2029

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
3a825ii	—	'Riboflavin' or 'Vitamin B ₂ '	<i>Additive composition</i> Riboflavin <i>Characterisation of the active substance</i> Riboflavin C ₁₇ H ₂₀ N ₄ O ₆ CAS number: 83-88-5 Riboflavin solid form produced by <i>Bacillus subtilis</i> DSM 17339 and/or DSM 23984 Purity criteria: min. 96 %, <i>Method of analysis</i> ⁽¹⁾ For the determination of Riboflavin in the feed additive: spectrophotometry at 444 nm (Ph.Eur.6.0, method 01/2008:0292) For the determination of Riboflavin in premixtures: high-Performance Liquid Chromatography coupled to UV detector, HPLC-UV (VDLUFA Bd.III, 13.9.1) For the determination of Riboflavin in feedingstuffs and water: high Performance Liquid Chromatography with Fluorescence detection, HPLC-FL (EN 14152)	All animal species	—	—	—	1. Riboflavin may be placed on the market and used as an additive consisting of a preparation. 2. May be used in water for drinking. 3. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	23 June 2029

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
3a 826		'Riboflavin 5'-phosphate monosodium salt' or 'Vitamin B ₂ '	<i>Additive composition</i> Riboflavin 5'-phosphate ester monosodium salt <i>Characterisation of the active substance</i> Riboflavin 5'-phosphate monosodium salt C ₁₇ H ₂₂ N ₄ O ₉ PNa CAS number: 130-40-5 Riboflavin 5'-phosphate ester monosodium salt solid form produced after phosphorylation of riboflavin 98 % produced by <i>Bacillus subtilis</i> DSM 17339 and/or DSM 23984. Purity criteria: min. 65 %, <i>Method of analysis</i> ⁽¹⁾ For the determination of Riboflavin 5'-phosphate monosodium salt in feed additive: spectrophotometry method at 444 nm (Ph.Eur.6.0, method 01/2008:0786) For the determination of Riboflavin in premixtures: high-Performance Liquid Chromatography coupled to UV detector, HPLC-UV (VDLUFA Bd.III, 13.9.1) For the determination of Riboflavin 5'-phosphate monosodium salt (as total Vitamin B ₂) in feedingstuffs and water: high Performance Liquid Chromatography with Fluorescence detection, HPLC-FL (EN 14152)	All animal species	—	—	—	1. May be used in water for drinking. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation,dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	23 June 2029

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2019/902

of 28 May 2019

on a measure taken by Sweden pursuant to Directive 2006/42/EC of the European Parliament and of the Council to prohibit the placing on the market of a scissor lift for vehicles (model TL530LF) manufactured by TWA Equipment S.r.l.

(notified under document C(2019) 3886)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC ⁽¹⁾, and in particular the second subparagraph of Article 11(3) thereof,

Whereas:

- (1) On 20 July 2017, Sweden informed the Commission of a measure that it had taken pursuant to Article 11(1) of Directive 2006/42/EC to prohibit the placing on the market of a scissor lift for vehicles (model TL530LF) manufactured by TWA Equipment S.r.l., Via Inn s.n.c. 65015, Montesilvano (PE), Italy (hereinafter 'the manufacturer') and distributed by Lidköpings Carpart AB, Plastagan 12C, 53155 Lidköping, Sweden (hereinafter 'Carpart').
- (2) Sweden took the measure because it considered that the scissor lift for vehicles did not satisfy the essential health and safety requirement set out in point (c) of Section 4.1.2.6 of Annex I to Directive 2006/42/EC. That provision requires machinery to be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine. Sweden justified the measure taken by it on the grounds that the pipe rupture valve did not work properly, affecting the safe functioning of the loading devices and posing potentially serious safety hazards as a result. In addition, Sweden argued that certain safety features were disabled (namely, the pressure-sensing valves) when the lift was lowered using the 'complete lowering' button and this could result in the runways becoming uneven.
- (3) After receiving notification of the safeguard measure taken by Sweden, the Commission entered into consultation with the parties concerned in order to hear their views. The Commission sent a letter to the manufacturer on 12 August 2017, to which the manufacturer did not reply. Based on the information communicated from the Swedish authorities to the Commission, Carpart is no longer supplying the product in question on the Swedish market. Furthermore, Carpart noted that it was in the process of replacing the factory-installed pipe rupture valves with improved pipe rupture valves on the TWA vehicle lifts model TL530LF that have already been supplied in Sweden. The Swedish authorities welcomed the actions taken by Carpart to improve the safety of the TL530LF model.
- (4) The explanations provided by Sweden and the documentation available to the Commission demonstrate that the scissor lift for vehicles model TL530LF fails to satisfy the essential health and safety requirement set out in point (c) of Section 4.1.2.6 of Annex I to Directive 2006/42/EC.
- (5) The measure taken by Sweden is necessary to ensure that the scissor lift for vehicles model TL530LF does not pose potentially serious safety hazards due to the malfunctioning of the pipe rupture valve or the disabling of certain safety features. Only a prohibition will ensure that the product is not placed on the market until the relevant essential health and safety requirement has been satisfied.
- (6) Therefore, the safeguard measure taken by Sweden is suitable, necessary and proportionate and should be considered justified,

⁽¹⁾ OJ L 157, 9.6.2006, p. 24.

HAS ADOPTED THIS DECISION:

Article 1

The measure taken by Sweden to prohibit the placing on the market of a scissor lift for vehicles (model TL530LF) manufactured by TWA Equipment S.r.l., Via Inn s.n.c. 65015, Montesilvano (PE) Italy and distributed by Lidköpings Carpart AB, Plastagan 12C, 53155 Lidköping, Sweden is justified.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 28 May 2019.

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2019/903**of 29 May 2019****setting the Union-wide performance targets for the air traffic management network for the third reference period starting on 1 January 2020 and ending on 31 December 2024****(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 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) ⁽¹⁾, and in particular point (a) of Article 11(3) thereof,

Whereas:

- (1) Regulation (EC) No 549/2004 requires the Commission to adopt for each reference period Union-wide performance targets in the key performance areas of safety, environment, capacity and cost-efficiency. Implementing rules regarding those targets have been set out in Commission Implementing Regulation (EU) 2019/317 ⁽²⁾. In particular, paragraph 4 of Article 9 of Implementing Regulation (EU) 2019/317 requires the Commission to adopt, together with the Union-wide performance targets, the following values: a Union-wide 'baseline value for determined costs', a Union-wide 'baseline value for the determined unit cost', alert thresholds beyond which Member States may request a revision of the performance targets contained in performance plans as well as the comparator groups of air navigation service providers with a similar operational and economic environment. The setting of determined costs is based on Article 15 of Regulation (EC) No 550/2004 of the European Parliament and of the Council ⁽³⁾.
- (2) The Union-wide performance targets for the third reference period ('RP3'), which covers the calendar years 2020 to 2024 inclusive, Union-wide baseline values, alert thresholds and the comparator groups should be established prior to 1 June 2019 allowing time for the preparation of performance plans, which should be submitted to the Commission by 1 October 2019 for their assessment.
- (3) On 16 December 2016, the Commission designated a Performance Review Body of the Single European Sky, in accordance with Article 11(2) of Regulation (EC) No 549/2004 and Commission Implementing Decision (EU) 2016/2296 ⁽⁴⁾, to assist it in implementing the performance scheme.
- (4) To facilitate the adoption of Union-wide performance targets for RP3, the Performance Review Body, on behalf of the Commission, carried out a stakeholder consultation between 20 June 2018 and 16 January 2019. It included all stakeholders listed in Article 10(3) of Regulation (EC) No 549/2004, including airspace users, air navigation service providers and professional staff representative bodies, on indicative performance target ranges and on the approach and methodology for setting performance targets as well as other values.
- (5) The Performance Review Body presented to the Commission its final report on 22 February 2019. That report takes into account changes that were introduced by Implementing Regulation (EU) 2019/317, relevant comments from stakeholders and the latest statistics and forecast for RP3 made available by Eurocontrol's Statistics and Forecast Service ('STATFOR') and Central Route Charges Office. The report by the Performance Review Body sets out the assumptions and the rationale underlying the proposed targets, the baseline values, the alert thresholds and the comparator groups.

⁽¹⁾ OJ L 96, 31.3.2004, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2019/317 of 11 February 2019 laying down a performance and charging scheme in the Single European Sky and repealing Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013 (OJ L 56, 25.2.2019, p. 1).

⁽³⁾ Regulation (EC) No 550/2004 of the European Parliament and of the Council of 10 March 2004 on the provision of air navigation services in the Single European Sky (the service provision Regulation) (OJ L 96, 31.3.2004, p. 10).

⁽⁴⁾ Commission Implementing Decision (EU) 2016/2296 of 16 December 2016 setting up the independent group of experts designated as Performance Review Body of the single European sky (OJ L 344, 17.12.2016, p. 92).

- (6) The Union-wide performance targets set out in this Decision take into account the input received from the Performance Review Body, the Network Manager, the European Union Aviation Safety Agency ('EASA'), and the national supervisory authorities. The Commission also organised, during January and February 2019, meetings and exchanges with Member States, national supervisory authorities, the Network Manager and the Performance Review Body to share latest information relevant for the performance target setting. In those discussions, Member States were invited to update the initial cost data and information about traffic forecasts. The performance targets set out in this Decision take into account this information.
- (7) The Union-wide performance targets and baseline values are based on data covering the geographical scope of the Member States, Norway and Switzerland and use *en route* traffic forecast expressed in terms of Instrument Flight Rules ('IFR') movements and in service units based on Eurocontrol's STATFOR base forecast, dated 18 February 2019. This *en route* traffic forecast corresponds to 10 534 000 IFR movements and 139 141 000 service units for 2019, 10 824 000 IFR movements and 143 878 000 service units for 2020, 10 996 000 IFR movements and 146 980 000 service units for 2021, 11 191 000 IFR movements and 150 398 000 service units for 2022, 11 355 000 IFR movements and 153 368 000 service units for 2023, and 11 523 000 IFR movements and 156 359 000 service units for 2024.
- (8) The setting of Union-wide performance targets should take into account economic, safety, environmental and operational considerations. A balance is required to ensure that disbenefits, or a combination of disbenefits, do not outweigh anticipated benefits. Therefore, Union-wide performance targets for RP3 should take into account interdependencies or trade-offs between key performance areas. Indeed, the performance targets in the key performance areas of cost-efficiency and capacity should take into account the relationship between costs to provide additional capacity and the improvements those costs can deliver. The performance targets in the key performance area of environment should take into account that air traffic management ('ATM') operational measures aiming to minimise fuel consumption, and to therefore reduce emissions, cannot always be implemented in practice. This is due to operational restrictions related to, in particular, safe separation of aircraft and the available ATM capacity. Finally, the performance targets in the key performance area of safety should take account of the fact that the provision of air navigation services in a safe way is an overriding objective and that safety should be fully embedded into the business planning of air navigation service providers.
- (9) The Union-wide performance targets set out in this Decision reflect the ambition for performance of the network as a whole. In accordance with Articles 14 and 15 of Implementing Regulation (EU) 2019/317, the Commission takes into account local circumstances when assessing the consistency of the national performance targets or Functional Airspace Block ('FAB') performance targets contained in the draft performance plans with the Union-wide performance targets contained in this Decision.
- (10) The Union-wide performance targets in the key performance area of safety, developed in collaboration with EASA, should be measured as the minimum level of the effectiveness of safety management to be achieved by air navigation service providers certified to provide air traffic services. These performance targets should take account of actual and targeted performance in the second reference period and go beyond minimum compliance with the requirements for the elements of the safety management system. Furthermore, the Commission entrusted EASA with a task to update compliance and guidance material to monitor and ensure the correct implementation of the safety indicators set out in point 1 of Section 1 and point 1 of Section 2 of Annex I to Implementing Regulation (EU) 2019/317. As a result, the framework used to measure the levels of the effectiveness of safety management is more stringent than in the second reference period, which is reflected in the approach taken to set the Union-wide performance targets in the key performance area of safety for RP3. These targets should also take into account the safety management implications of ATM changes promoted by the implementation of SESAR projects referred to in Article 15a(3) of Regulation (EC) No 550/2004, by focusing on the safety assurance and safety risk management objectives.
- (11) The Union-wide performance targets in the key performance area of environment, measured as the average horizontal *en route* flight efficiency of the actual trajectory, should take account of the level of performance achieved in the second reference period, the measures implemented to optimise ATM operations and relevant inputs from the Performance Review Body, the Network Manager and the national supervisory authorities.

- (12) The environmental impact of aviation is increasing but at a lower rate than expected considering the growth in the number of flights over the second reference period. The extra gate-to-gate CO₂ emissions caused by ATM network inefficiency, calculated by comparing the actual trajectories and the unimpeded trajectories of all European flights, have remained stable at about 6 % over the last six years despite the growth in number of flights, thanks to optimisation of ATM operations related to design, planning and flow and capacity management of the European ATM network. Horizontal *en route* flight inefficiency has been decreasing overall and the performance target set for the second reference period is expected to be met.
- (13) Improvements in the key performance area of environment are driven mainly by the implementation of Free Route Airspace ('FRA'), which enables shorter routes and a more efficient use of the European airspace. It is expected that FRA will be implemented in most of the European airspace by the end of 2019, and in its totality by 2022. Combined with the gradual implementation of cross-border free route activities, this can lead to more direct routing and can reduce the number of nautical miles flown and emissions caused by air traffic, thereby supporting a sustainable reduction of the carbon intensity of aviation. This gradual implementation justifies therefore an improvement in the horizontal *en route* flight efficiency until 2022. After 2022, the horizontal *en route* flight efficiency should remain stable. From the measures currently foreseen and considering that aircraft need to avoid increasingly frequent adverse weather and danger areas and considering that ATM operations have to ensure minimum separation between aircraft, it is not expected that horizontal *en route* flight efficiency further improves in 2023 and 2024.
- (14) The Union-wide performance target in the key performance area of capacity, measured as the average *en route* air traffic flow management ('ATFM') delay per flight attributable to air navigation services, should take account of the level of performance achieved in the second reference period, and of relevant input from the Performance Review Body, the Network Manager and the national supervisory authorities.
- (15) As documented by the Network Manager, air traffic in Europe has grown significantly over the second reference period and is now at a historic high. IFR movements increased by 13 % in the first four years of the second reference period and *en route* average ATFM delay rose from 0,73 minute per flight in 2015 to 1,73 minute per flight in 2018, which represents a 137 % increase in delay. In some areas of the Union, in particular in a limited number of area control centres in the core area of Europe and in adjacent areas in Central Europe, ATM capacity was not sufficient to accommodate this growth in traffic. Five area control centres are responsible for more than half of the total *en route* ATFM delay attributed to Air Traffic Control (ATC) capacity and staffing in Europe, and some of those centres have not complied with the capacity plans agreed in the Network Operations Plan ('NOP'). This led to the situation that the Union-wide performance target for the second reference period of 0,5 minute average ATFM delay per flight was not met. The capacity shortage is expected to worsen in the next years.
- (16) Considering the traffic forecast for RP3, according to the Network Manager and the Performance Review Body, most of the air navigation service providers are expected to be capable to deliver their capacity requirements for RP3. However, according to information transmitted by national supervisory authorities, the service quality proposed by the air navigation service providers in the NOP is expected to remain problematic for some area control centres due to inappropriate staffing levels in particular, especially in the first three years of RP3. As a result, reaching the system-wide optimum average ATFM delay of 0,5 minute per flight can only be expected at the end of RP3. To address the capacity shortage and to meet the targets set in this Decision, the Network Manager and the Performance Review Body recommend that air navigation service providers take specific actions at the level of concerned area control centres.
- (17) The Union-wide performance targets in the key performance area of cost-efficiency for each year of the reference period should be expressed as a percentage, reflecting the year-on-year change of the average Union-wide 'determined unit cost' ('DUC') for *en route* air navigation services. The Union-wide performance targets in the key performance area of cost-efficiency should take account of the level of performance achieved in the first and second reference periods and of relevant input from the Performance Review Body and the national supervisory authorities.

- (18) At Union-wide level, since the beginning of the first reference period in 2012, *en route* actual costs expressed in EUR2017 have remained constant in spite of the significant increase in traffic. Actual costs for the first three years of the second reference period are below the corresponding determined costs. As a result, the aggregate surplus of air navigation service providers at Union-wide level has been higher than planned. This, together with the analysis conducted by the Performance Review Body, gives an indication that most air navigation service providers can achieve further cost-efficiency improvements in RP3, while also addressing the capacity needs. At the same time, air traffic and *en route* ATFM delays have increased significantly in recent years, which may indicate that insufficient resources have been invested in the network during the second reference period. The cost-efficiency targets for RP3 should aim at cost-efficiency improvements, while ensuring that these improvements are not to the detriment of providing sufficient capacity.
- (19) Airspace users expressed concerns about cancelled or delayed investment projects to provide necessary capacity. The costs stemming from such projects were often partly or wholly included in the determined costs of previous reference periods and thus included in the charges. Where air navigation service providers generated part of their surplus from not implemented or from delayed implementation of necessary investments, those surpluses could serve to finance necessary investments in RP3, if they have not been paid out as dividends to shareholders or to the state budget. Furthermore, when setting the interest rates for the purpose of calculation of capital costs, air navigation service providers should take into account the limitations of risks for the air navigation service providers under the traffic and cost risk sharing mechanisms and the generally favourable financing conditions.
- (20) The expected improvement in cost-efficiency for the RP3 should be calculated starting from the Union-wide baseline value for the determined unit cost, which is derived by dividing the baseline value for the determined costs with the traffic forecast expressed in service units for the year 2019. The baseline value for Union-wide determined costs is estimated by using the actual costs for the years 2015, 2016 and 2017 through a linear regression analysis and is adjusted to take account of the latest available cost estimates, traffic variations and their relation to costs.
- (21) The determined costs at Union-wide level for RP3 should only slightly increase over RP3, above the level of the baseline value for determined costs. This is justified to improve service quality, in particular by addressing the capacity shortage in the European airspace. Over a time period covering both RP3 and the second reference period, the year-on-year change of the average Union-wide determined unit cost for *en route* air navigation services should amount to – 2,7 % per year.
- (22) In addition to the Union-wide performance targets, alert thresholds beyond which Member States may request a revision of the performance targets contained in performance plans should be established. Implementing Regulation (EU) 2019/317 provides for three different types of thresholds, based on the following parameters: deviations of actual traffic from traffic forecast over a given calendar year expressed in percentage of IFR movements, deviations of actual traffic from traffic forecast over a given calendar year expressed as a percentage of service units and the variation of reference values as a result of seasonal updates of the NOP. Variations in the underlying factors of those alert thresholds may have significant impacts on the provision of air navigation services, both on the side of actual revenues, as well as expectations in terms of capacity provision.
- (23) To establish the alert thresholds, consideration should be given to the traffic forecast ranges, in terms of *en route* service units and IFR movements, from low to high growth based on Eurocontrol's STATFOR. The long forecasting period until the end of 2024 involves a degree of uncertainty, in particular related to economic growth, the United Kingdom's intention to leave the Union, geopolitical risks that may result in closures of airspace and variability in traffic flows as witnessed during the second reference period as well as the development of economic ties with emerging markets. Those risks are taken into account in the forecasts, on the basis of the information available until February 2019. However, the economic outlook remains uncertain and the weight of risk is highly variable.
- (24) In addition to the Union-wide performance targets, comparator groups of air navigation service providers with a similar operational and economic environment should be established for the purpose of assessing performance targets in the key performance area of cost-efficiency. To establish those groups, the complexity of the airspace, the levels and variability of traffic, the cost of living, and the unit air traffic controllers' employment cost for each air navigation service provider should be taken into account.

- (25) The values of the Union-wide performance targets and those of the alert thresholds established at the moment of adoption of this Implementing Decision, should not vary even if Union law ceases to apply to the United Kingdom at a later date and no withdrawal agreement has entered into force. Indeed, that possible event would not substantially affect the determination of those values. Union-wide performance targets in the key performance area of safety are determined by factors that are independent from the number of Member States. Union-wide performance targets in the key performance area of environment depend upon trajectories, but whether those trajectories involve the airspace of Member States only or also of third countries is not relevant. For Union-wide performance targets in the key performance areas of capacity and cost-efficiency, calculations have shown that the impact of the United Kingdom leaving the Union would be negligible and that therefore no changes to those targets would be required under either scenario. However, the baseline value for the determined costs, the baseline value for the determined unit cost and the comparator groups should depend upon whether Union law or a withdrawal agreement applies to the United Kingdom on the day of the entry into force of this Implementing Decision, or whether none of those two scenarios applies.
- (26) The measures provided for in this Decision are in accordance with the opinion of the Single Sky Committee,

HAS ADOPTED THIS DECISION:

Article 1

Scope

This Decision applies to the third reference period referred to in Article 7 of Implementing Regulation (EU) 2019/317.

Article 2

Union-wide performance targets in the key performance area of safety

Union-wide performance targets in the key performance area of safety, as referred to in point 1.1 of Section 1 of Annex I to Implementing Regulation (EU) 2019/317, to be achieved by the end of 2024 by air navigation service providers certified to provide services are set at the following levels of effectiveness of safety management:

- (a) at least Level C in the safety management objectives 'safety culture', 'safety policy and objectives', 'safety assurance', and 'safety promotion';
- (b) at least Level D in the safety management objective 'safety risk management'.

Article 3

Union-wide performance targets in the key performance area of environment

Union-wide performance targets for the key performance area of environment, as defined in point 2.1 of Section 1 of Annex I to Implementing Regulation (EU) 2019/317, shall be expressed as an average horizontal *en route* flight efficiency of the actual trajectory and measured as average additional distance flown compared to the great circle distance and shall not exceed the following percentages: 2,53 % in 2020, 2,47 % in 2021, 2,40 % in 2022, 2,40 % in 2023 and 2,40 % in 2024.

Article 4

Union-wide performance targets in the key performance area of capacity

Union-wide performance targets for the key performance area of capacity, in accordance with point 3.1 of Section 1 of Annex I to Implementing Regulation (EU) 2019/317, shall be an average *en route* ATFM delay attributable to air navigation services of a maximum of 0,9 minute per flight in 2020, 0,9 minute per flight in 2021, 0,7 minute per flight in 2022, 0,5 minute per flight in 2023 and 0,5 minute per flight in 2024.

Article 5

Union-wide performance targets in the key performance area of cost-efficiency

1. Union-wide performance targets for the key performance area of cost-efficiency, as defined in point 4.1 of Section 1 of Annex I to Implementing Regulation (EU) 2019/317, shall be a year-on-year change of the average Union-wide determined unit cost for *en route* air navigation services of – 1,9 % for 2020, – 1,9 % for 2021, – 1,9 % for 2022, – 1,9 % for 2023 and – 1,9 % for 2024. The year-on-year change shall be calculated starting from the baseline value for the determined unit cost set in paragraph 3.
2. The baseline value for determined costs shall be set at:
 - (a) EUR 6 245 065 000 in EUR2017 in the case where Union law ceases to apply to the United Kingdom at a date prior to the date of entry into force of this Implementing Decision and no withdrawal agreement concluded with the United Kingdom has entered into force by that date;
 - (b) EUR 7 047 092 000 in EUR2017 in all other cases.
3. The baseline value for the determined unit cost shall be set at:
 - (a) EUR 49,29 in EUR2017 in the case where Union law ceases to apply to the United Kingdom at a date prior to the date of entry into force of this Implementing Decision and no withdrawal agreement concluded with the United Kingdom has entered into force by that date.
 - (b) EUR 50,65 in EUR2017 in all other cases.

Article 6

Alert thresholds

1. Member States may request a revision of one or more performance targets contained in the performance plans, in accordance with point (a)(i) of Article 18(1) of Implementing Regulation (EU) 2019/317, where:
 - (a) the actual traffic, recorded by Eurocontrol, deviates from the traffic forecast in the performance plan adopted in accordance with Article 16 of Implementing Regulation (EU) 2019/317 over a given calendar year by at least 10 % of IFR movements;
 - (b) the actual traffic, recorded by Eurocontrol, deviates from the traffic forecast in the performance plan adopted in accordance with Article 16 of Implementing Regulation (EU) 2019/317 over a given calendar year by at least 10 % of service units.
2. Member States may request a revision of one or more performance targets contained in the performance plans, in accordance with point (a)(i) of Article 18(1) of Implementing Regulation (EU) 2019/317, where the variation of the reference values as a result of the seasonal updates of the NOP pursuant to point (a) of Article 9(4) and Article 9(8) of Commission Implementing Regulation (EU) 2019/123 ⁽⁹⁾ in comparison to the reference values from the latest version of the NOP available at the time of drawing up the performance plan is at least:
 - (a) 0,05 minute of *en route* ATFM delay if the reference value from the latest version of the NOP available at the time of drawing up the performance plan is less than 0,2 minute of *en route* ATFM delay; or
 - (b) 0,04 minute of *en route* ATFM delay increased by 5 % of the reference value from the latest version of the NOP available at the time of drawing up the performance plan if the reference value is greater than or equal to 0,2 minute of *en route* ATFM delay.

⁽⁹⁾ Commission Implementing Regulation (EU) 2019/123 of 24 January 2019 laying down detailed rules for the implementation of air traffic management (ATM) network functions and repealing Commission Regulation (EU) No 677/2011 (OJ L 28, 31.1.2019, p. 1).

*Article 7***Comparator Groups**

The comparator groups of air navigation service providers with a similar operational and economic environment for the purpose of assessing performance targets in the key performance area of cost-efficiency shall be set as follows:

- (a) in the case where Union law ceases to apply to the United Kingdom at a date prior to the date of entry into force of this Implementing Decision and no withdrawal agreement concluded with the United Kingdom has entered into force by that date:
 - (i) Group A: the air navigation service providers of Germany, France, Spain and Italy;
 - (ii) Group B: the air navigation service providers of Norway, Sweden, Denmark, Finland and Ireland;
 - (iii) Group C: the air navigation service providers of Czechia, Croatia, Slovenia, Hungary, Slovakia, Bulgaria, Poland, Romania and Portugal;
 - (iv) Group D: the air navigation service providers of Cyprus, Malta, Estonia, Latvia, Lithuania and Greece;
 - (v) Group E: the air navigation service providers of Austria, Switzerland, Belgium-Luxembourg and the Netherlands;
- (b) in all other cases:
 - (i) Group A: the air navigation service providers of Germany, United Kingdom, France, Spain and Italy;
 - (ii) Group B: the air navigation service providers of Norway, Sweden, Denmark, Finland and Ireland;
 - (iii) Group C: the air navigation service providers of Czechia, Croatia, Slovenia, Hungary, Slovakia, Bulgaria, Poland, Romania and Portugal;
 - (iv) Group D: the air navigation service providers of Cyprus, Malta, Estonia, Latvia, Lithuania and Greece;
 - (v) Group E: the air navigation service providers of Austria, Switzerland, Belgium-Luxembourg and the Netherlands.

Article 8

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

Done at Brussels, 29 May 2019.

For the Commission
The President
Jean-Claude JUNCKER

