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⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1294

of 4 August 2021

cancelling the protection of the designation of origin ('Südburgenland (PDO)')

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 106 thereof,

Whereas:

- (1) Article 19 of Commission Delegated Regulation (EU) 2019/33 ⁽²⁾ provides that the procedure laid down in Article 94 and Articles 96 to 99 of Regulation (EU) No 1308/2013 shall apply *mutatis mutandis* to the cancellation of a protected designation of origin under Article 106 of Regulation (EU) No 1308/2013.
- (2) Pursuant to Article 19 of Delegated Regulation (EU) 2019/33, Austria's request to cancel the protected designation of origin 'Südburgenland' was published in the *Official Journal of the European Union* ⁽³⁾.
- (3) As no statement of objection under Article 98 of Regulation (EU) No 1308/2013 has been received by the Commission, the protected designation of origin 'Südburgenland' should be cancelled.
- (4) In view of the cancellation of the protection of the designation of origin 'Südburgenland', the entry should be deleted from the Union register of protected designations of origin and protected geographical indications for wine referred to in Article 104 of Regulation (EU) No 1308/2013.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The protection of the designation of origin 'Südburgenland' (PDO) is hereby cancelled.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ Commission Delegated Regulation (EU) 2019/33 of 17 October 2018 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation (OJ L 9, 11.1.2019, p. 2).

⁽³⁾ OJ C 57, 17.2.2021, p. 30.

Article 2

The entry for the designation of origin 'Südburgenland' (PDO) is hereby deleted from the register of protected designations of origin and protected geographical indications for wine.

Article 3

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, 4 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1295**of 4 August 2021****derogating in respect of the year 2021 from Article 75(1), third subparagraph, of Regulation (EU) No 1306/2013 of the European Parliament and of the Council as regards the level of advance payments for direct payments and area-related and animal-related rural development measures**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ⁽¹⁾, and in particular Article 75(3) thereof,

Whereas:

- (1) Pursuant to Article 75(1), third subparagraph, of Regulation (EU) No 1306/2013, from 16 October to 30 November Member States may pay advances of up to 50 % for direct payments under Regulation (EU) No 1307/2013 of the European Parliament and of the Council ⁽²⁾ and prior to 1 December they may pay advances of up to 75 % for area-related and animal-related support measures under Regulation (EU) No 1305/2013 of the European Parliament and of the Council ⁽³⁾.
- (2) Due to the crisis resulting from the COVID-19 pandemic in the Member States, farmers have encountered exceptional economic and financial difficulties. Considering the specific vulnerability of those economic operators and in order to mitigate financial and cash flow consequences of that crisis, Commission Implementing Regulation (EU) 2020/531 ⁽⁴⁾ provided for a derogation from Article 75(1), third subparagraph, of Regulation (EU) No 1306/2013 by allowing Member States to pay a higher level of advances to beneficiaries for the year 2020. As the COVID-19 pandemic still persists in 2021 and farmers are still facing economic disruptions, Member States should be allowed to continue paying increased advance payments in respect of claim year 2021.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Committee on the Agricultural Funds, the Committee for Direct Payments and the Rural Development Committee,

HAS ADOPTED THIS REGULATION:

Article 1

By way of derogation from Article 75(1), third subparagraph, of Regulation (EU) No 1306/2013, in respect of claim year 2021 Member States may pay advances of up to 70 % for the direct payments listed in Annex I to Regulation (EU) No 1307/2013 and of up to 85 % for the support granted under rural development as referred to in Article 67(2) of Regulation (EU) No 1306/2013.

⁽¹⁾ OJ L 347, 20.12.2013, p. 549.

⁽²⁾ Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).

⁽³⁾ Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/531 of 16 April 2020 derogating in respect of the year 2020 from the third subparagraph of Article 75(1) of Regulation (EU) No 1306/2013 of the European Parliament and of the Council as regards the level of advance payments for direct payments and area-related and animal-related rural development measures and from the first subparagraph of Article 75(2) of that Regulation as regards direct payments (OJ L 119, 17.4.2020, p. 1).

Article 2

This Regulation shall enter into force on the third 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, 4 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1296**of 4 August 2021****amending and correcting Regulation (EU) No 965/2012 as regards the requirements for fuel/energy planning and management, and as regards requirements on support programmes and psychological assessment of flight crew, as well as testing of psychoactive substances****(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 31 thereof,

Whereas:

- (1) Commission Regulation (EU) No 965/2012 ⁽²⁾ lays down detailed rules for air operations and in particular for fuel planning and management. Those rules should be updated to reflect recent advances in engine technology and best practices in the domain of air operations, and to take into account worldwide aviation experience and scientific and technical progress in air operations.
- (2) The latest fuel-related amendments to Annex 6 of the Convention on International Civil Aviation (ICAO), being Part I (11th edition), Part III (9th edition) and the new guidance of ICAO Document 9976 'Fuel planning manual' should be incorporated in Regulation (EU) No 965/2012, with the exception of certain requirements applicable to helicopters, where other solutions are considered by EASA as meeting the required level of safety.
- (3) The new rules on fuel/energy planning and management should allow for a level playing field for all interested parties in the internal aviation market and improve competitiveness of the Union aviation industry.
- (4) The new fuel/energy planning and management requirements should support innovation and allow for the smooth integration of new technologies into the air operations domain. Therefore, the term 'fuel/energy' should be used instead of the term 'fuel', wherever appropriate, to accommodate operations with aircraft that use other energy sources than conventional hydrocarbon-based fuel.
- (5) The requirements related to the different types of operations should be proportionate to the scale and complexity of such operations, as well as to the risks involved in such operations.
- (6) Air operators should be able to use a performance-based planning and management procedures that improve operational efficiency by producing financial and environmental benefits, while maintaining or even improving the level of safety. Therefore, the new requirements for aeroplanes used in commercial air transport (CAT) operations should introduce a comprehensive fuel scheme encompassing three main policies related to fuel: fuel/energy planning, aerodrome selection and in-flight fuel and energy management. This should allow a more flexible management of risk by the operator, leading to potential efficiency gains.

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).

- (7) Safety information collected by EASA suggests that new requirements should be introduced to address the risks associated with refuelling, and more specifically when refuelling with passengers on board, disembarking or embarking, and when refuelling a helicopter with rotors turning.
- (8) The assessment of complex fuel/energy schemes requires enhanced capabilities from the competent authorities, therefore it is necessary to introduce criteria to guide competent authorities when making operational safety risk assessments to support the application of fully performance-based fuel/energy schemes.
- (9) Following the principles of proportionality and better regulation, the fuel and energy requirements for non-commercial operations with complex motor-powered aircraft (NCC) and for specialised operations (SPO) should be better aligned with those for CAT operations. On the other hand, the fuel and energy requirements for non-commercial operators of other-than-complex motor-powered aircraft should be based on safety objectives and should allow a performance-based approach. The new requirements on fuel and energy planning and management should reduce regulatory burden, increase cost-effectiveness and, with some exceptions, lead to harmonisation with requirements laid down by ICAO.
- (10) Commission Regulation (EU) 2018/1042 ⁽³⁾ added to Regulation (EU) No 965/2012 requirements for support programmes, the psychological assessment of flight crew and the systematic and random testing of psychoactive substances to ensure the medical fitness of flight crew and cabin crew members. Those requirements have become applicable in February 2021. The Agency was mandated to continuously evaluate the effectiveness of the new provisions and produce a first evaluation report by August 2022. Taking into account the impact of the Covid-19 pandemic on aviation, it is advisable to allow for more time for the Agency to collect the relevant data for the evaluation. Therefore, it is necessary to postpone the deadline for the completion of the evaluation report to 14 August 2023.
- (11) Regulation (EU) 2018/1042 introduced into Annex I to Regulation (EU) No 965/2012 a point 98(a) which defined the term 'psychoactive substances'. Commission Implementing Regulation (EU) 2020/2036 ⁽⁴⁾, which subsequently amended Annex I to Regulation (EU) No 965/2012, inadvertently replaced point 98(a) by new text, defining the term 'proficient', and deleted the definition of the term 'psychoactive substances'. That definition is essential for the consistent interpretation of the provisions introduced by Regulation (EU) 2018/1042 and in particular to clearly define which substances are subject to those provisions and which are not. Therefore, in order to safeguard legitimate expectations of the persons subject to those provisions that definition should be reintroduced in Annex I to Regulation (EU) No 965/2012 with effect from the date of application of the related changes introduced by Regulation (EU) 2018/1042, that is from 14 February 2021.
- (12) The European Union Aviation Safety Agency has prepared a draft implementing rule and submitted it with Opinion 02/2020 ⁽⁵⁾ in accordance with Article 75(2), points (b) and (c), and Article 76(1) of Regulation (EU) 2018/1139.
- (13) Regulation (EU) No 965/2012 should therefore be amended and corrected accordingly.
- (14) In order to ensure the proper implementation of this Regulation, Member States and affected stakeholders should be given sufficient time to adapt their procedures to the new requirements established by this Regulation. Therefore, its application should be deferred.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Committee established in accordance with Article 127 of Regulation (EU) 2018/1139,

⁽³⁾ Commission Regulation (EU) 2018/1042 of 23 July 2018 amending Regulation (EU) No 965/2012, as regards technical requirements and administrative procedures related to introducing support programmes, psychological assessment of flight crew, as well as systematic and random testing of psychoactive substances to ensure medical fitness of flight and cabin crew members, and as regards equipping newly manufactured turbine-powered aeroplanes with a maximum certified take-off mass of 5 700 kg or less and approved to carry six to nine passengers with a terrain awareness warning system (OJ L 188, 25.7.2018, p. 3).

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/2036 of 9 December 2020 amending Regulation (EU) No 965/2012 as regards the requirements for flight crew competence and training methods and postponing dates of application of certain measures in the context of the COVID-19 pandemic (OJ L 416, 11.12.2020, p. 24).

⁽⁵⁾ <https://www.easa.europa.eu/document-library/opinions>

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 965/2012

Regulation (EU) No 965/2012 is amended as follows:

(1) in Article 9b, the second paragraph is replaced by the following:

‘The Agency shall conduct a continuous review of the effectiveness of the provisions concerning support programmes, the psychological assessment of flight crew and the systematic and random testing of psychoactive substances to ensure the medical fitness of flight crew and cabin crew members set out in Annexes II and IV. No later than 14 August 2023, the Agency shall produce a first report on the results of this review.

That review shall involve relevant expertise and shall be based on data gathered, with the assistance of Member States and the Agency, on a long-term basis.’;

(2) Annexes I, II, III, IV, V, VI, VII and VIII are amended in accordance with Annex I to this Regulation.

Article 2

Correction of Regulation (EU) No 965/2012

Annex I to Regulation (EU) No 965/2012 is corrected in accordance with Annex II to this Regulation.

Article 3

Entry into force and application

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 30 October 2022.

However, Annex II shall apply from 14 February 2021.

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

Done at Brussels, 4 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annexes I, II, III, IV, V, VI, VII and VIII to Regulation (EU) No 965/2012 are amended as follows:

(1) Annex I is amended as follows:

(a) the following point (8c) is inserted:

‘(8c) ‘alternate aerodrome’ means an adequate aerodrome to which an aircraft may proceed when it becomes either impossible or inadvisable to proceed to or land at the aerodrome of intended landing, where the necessary services and facilities are available, where aircraft performance requirements can be met, and which is operational at the expected time of use; ‘alternate aerodrome’ includes the following:

- (a) ‘take-off alternate aerodrome’: an alternate aerodrome at which an aircraft would be able to land if it becomes necessary shortly after take-off and it is not possible to use the aerodrome of departure;
- (b) ‘en route alternate (ERA) aerodrome’: an alternate aerodrome at which an aircraft would be able to land if a diversion becomes necessary while en route;
- (c) ‘fuel/energy en route alternate (fuel/energy ERA) aerodrome’ means an ERA aerodrome that is required at the planning stage for use in the calculation of fuel/energy;
- (d) ‘destination alternate aerodrome’: an alternate aerodrome at which an aircraft would be able to land if it becomes either impossible or inadvisable to land at the aerodrome of intended landing;’;

(b) point (26) is replaced by the following:

‘(26) ‘contingency fuel/energy’ means the fuel/energy required to compensate for unforeseen factors that could have an influence on the fuel/energy consumption to the destination aerodrome;’;

(c) the following point (31a) is inserted:

‘(31a) ‘current fuel/energy scheme’ means the approved fuel/energy scheme that is currently used by the operator;’;

(d) point (46) is deleted;

(e) the following points (49d) and (49e) are inserted:

‘(49d) ‘flight following’ means the recording in real time of departure and arrival messages by operational personnel to ensure that a flight is operating and has arrived at the destination aerodrome or an alternate aerodrome;

(49e) ‘flight monitoring’ means, in addition to the requirements defined for flight following:

- (a) operational monitoring of flights by suitably qualified operational-control personnel from departure throughout all phases of the flight;
- (b) communication of all available and relevant safety information between the operational-control personnel on the ground and the flight crew; and
- (c) critical assistance to the flight crew in the event of an in-flight emergency or security issue, or at the request of the flight crew;’;

(f) the following points (50a) and (50b) are inserted:

‘(50a) ‘flight time’ means:

- (a) for aeroplanes, the total time from the moment an aeroplane first moves for the purpose of taking off until the moment the aeroplane finally comes to rest at the end of the flight;
- (b) for helicopters, the total time between the moment a helicopter’s rotor blades start turning for the purpose of taking off until the moment the helicopter finally comes to rest at the end of the flight, and the rotor blades are stopped;

(50b) 'flight watch' means, in addition to all elements defined for 'flight monitoring', the active tracking of a flight by suitably qualified operational-control personnel throughout all phases of the flight to ensure that the flight is following its prescribed route without unplanned deviations, diversions or delays;'

(g) point (51) is deleted;

(h) point (73) is replaced by the following:

'(73) 'local helicopter operation (LHO)' means a commercial air transport operation of helicopters with a maximum certified take-off mass (MCTOM) over 3 175 kg and a maximum operational passenger seating configuration (MOPSC) of nine or less, by day, over routes navigated by reference to visual landmarks, conducted within a local and defined geographical area specified in the operations manual;'

(i) the following point (104a) is inserted:

'(104a) 'safe landing' means, in the context of the fuel/energy policy or fuel/energy schemes, a landing at an adequate aerodrome or operating site with no less than the final reserve fuel/energy remaining and in compliance with the applicable operational procedures and aerodrome operating minima;'

(2) Annex II is amended as follows:

(a) point ARO.OPS.225 is replaced by the following:

'ARO.OPS.225 Approval of fuel/energy schemes

(a) The competent authority shall approve the fuel/energy scheme proposed by a CAT operator if the operator demonstrates compliance with all applicable requirements laid down in this Regulation related to fuel/energy for aeroplanes or helicopters involved in CAT.

(b) The competent authority shall assess and oversee the fuel/energy planning and in-flight re-planning, selection of aerodrome and, in-flight fuel/energy management policies associated with the fuel/energy schemes, together with the processes supporting the implementation of these fuel/energy schemes.

(c) In addition to points (a) and (b), when approving individual fuel/energy schemes, the competent authority shall:

(1) verify that the operator has demonstrated the baseline safety performance of the current fuel/energy scheme;

(2) assess the capability of the operator to support the implementation of the proposed individual fuel/energy scheme; the following elements shall be considered as a minimum:

(i) the operator's management system,

(ii) the operator's operational capabilities;

(3) verify that the operator's safety risk assessment that supports the proposed individual fuel/energy scheme achieves an equivalent level of safety to that of the current fuel/energy scheme; and

(4) establish an oversight plan to carry out periodic assessments of the approved individual fuel/energy scheme to verify compliance of the scheme or decide whether the scheme should be amended or revoked.

(d) The approval referred to in point CAT.OP.MPA.182 (d)(2) shall include a list of the isolated aerodromes that are specified by the operator for each aircraft type to which the approval applies.

(e) Without prejudice to points ARO.GEN.120 (d) and (e), the competent authority shall notify the Agency of the start of the evaluation of an alternative means of compliance related to fuel/energy schemes;'

(3) in Annex III, Appendix I is replaced by the following:

'Appendix I

DECLARATION

in accordance with Commission Regulation (EU) No 965/2012 on air operations

Operator

Name:

Place in which the operator has its principal place of business or, if the operator has no principal place of business, place in which the operator is established or residing and place from which the operations are directed:

Name and contact details of the accountable manager:

Aircraft operation

Starting date of operation and applicability date of the change:

Information on aircraft, operation, and continuing-airworthiness management organisation⁽¹⁾:

Type(s) of aircraft, registration(s) and main base:

Aircraft MSN ⁽²⁾	Aircraft type	Aircraft registration ⁽³⁾	Main base	Type(s) of operation ⁽⁴⁾	Organisation responsible for continuing-airworthiness management ⁽⁵⁾

The operator shall obtain a prior approval⁽⁶⁾ or specific approval⁽⁷⁾ for certain operations before conducting such operations.

Where applicable, details of approvals held (attach list of specific approvals, including specific approvals granted by a third country, if applicable).

Where applicable, details of specialised-operations authorisation held (attach authorisation(s)).

Where applicable, list of alternative means of compliance (AltMoC) with references to the AMC they replace (attach AltMoC).

Statements

- ☐ The operator complies, and will continue to comply, with the essential requirements set out in Annex V to Regulation (EU) 2018/1139 of the European Parliament and of the Council and with the requirements of Regulation (EU) No 965/2012.
- ☐ The management system documentation, including the operations manual, complies with the requirements of Annex III (Part-ORO), Annex V (Part-SPA), Annex VI (Part-NCC), or Annex VIII (Part-SPO) to Regulation (EU) No 965/2012 and all flights will be made in accordance with the provisions of the operations manual as required by point ORO.GEN.110 (b) of Annex III (Part-ORO).
- ☐ All operated aircraft hold a valid certificate of airworthiness in accordance with Commission Regulation (EU) No 748/2012 or meet the specific airworthiness requirements applicable to aircraft registered in a third country and subject to a lease agreement.

-
- ☐ All flight crew members hold a licence in accordance with Annex I to Commission Regulation (EU) No 1178/2011 as required by point ORO.FC.100 (c) of Annex III to Regulation (EU) No 965/2012, and cabin crew members, where applicable, are trained in accordance with Subpart CC of Annex III (Part-ORO).
-
- ☐ If applicable, the operator implements and demonstrates conformance to a recognised industry standard.
Reference of the standard:
Certification body:
Date of the last conformity audit:
-
- ☐ The operator will notify to the competent authority any changes in circumstances affecting its compliance with the essential requirements set out in Annex V to Regulation (EU) 2018/1139 and with the requirements of Regulation (EU) No 965/2012 as declared to the competent authority through this declaration, and any changes to the information on and lists of AltMoC included in and annexed to this declaration as required by point ORO.GEN.120 (a) of Annex III (Part-ORO).
-
- ☐ The operator confirms that the information disclosed in this declaration is correct.’
-

Date, name, and signature of the accountable manager

- ⁽¹⁾ If there is not enough space to list the required information in the declaration, the information shall be listed in a separate annex. The annex shall be dated and signed.
- ⁽²⁾ Manufacturer serial number.
- ⁽³⁾ If the aircraft is also registered with an air operator certificate (AOC) holder, specify the AOC number of the AOC holder.
- ⁽⁴⁾ ‘Type(s) of operation’ refers to the type of operations conducted with this aircraft, e.g. non-commercial operations or specialised operations, e.g. aerial photography flights, aerial advertising flights, news media flights, television and movie flights, parachute operations, skydiving, maintenance check flights.
- ⁽⁵⁾ Information about the organisation that is responsible for the continuing-airworthiness management shall include the name of the organisation, its address, and the approval reference.
- ⁽⁶⁾ (a) operations with any defective instrument or piece of equipment or item or function, under a minimum equipment list (MEL) (points ORO.MLR.105 (b), (f), and (j), NCC.IDE.A.105, NCC.IDE.H.105, SPO.IDE.A.105, and SPO.IDE.H.105).
(b) operations requiring prior authorisation or approval, including all of the following:
— for specialised operations, wet lease-in and dry lease-in of aircraft registered in a third country (point ORO.SPO.100 (c));
— high-risk commercial specialised operations (point ORO.SPO.110);
— non-commercial operations with aircraft with an MOPSC of more than 19, which are performed without an operating cabin crew member (point ORO.CC.100 (d));
— use of IFR operating minima that are lower than those published by the State (points NCC.OP.110 and SPO.OP.110);
— refuelling with engine(s) and/or rotors turning (points NCC.OP.157);
— specialised operations (SPO) without oxygen above 10 000 ft (point SPO.OP.195).
- ⁽⁷⁾ operations in accordance with Annex V (Part-SPA) to Regulation (EU) No 965/2012, including Subparts B ‘PERFORMANCE-BASED NAVIGATION (PBN) OPERATIONS’, C ‘OPERATIONS WITH SPECIFIED MINIMUM NAVIGATION PERFORMANCE (MNPS)’, D ‘OPERATIONS IN AIRSPACE WITH REDUCED VERTICAL SEPARATION MINIMA (RVSM)’, E ‘LOW VISIBILITY OPERATIONS (LVO)’, G ‘TRANSPORT OF DANGEROUS GOODS’, K ‘HELICOPTER OFFSHORE OPERATIONS’, and M ‘ELECTRONIC FLIGHT BAGS (EFBs)’.
-

(4) Annex IV is amended as follows:

- (a) point CAT.OP.MPA.100 (b)(3) is replaced by the following:
‘CAT.OP.MPA.100 Use of air traffic services
‘(3) local helicopter operations (LHOs),’;
- (b) point CAT.OP.MPA.106 is deleted;
- (c) point CAT.OP.MPA.150 is replaced by the following:
‘CAT.OP.MPA.150
INTENTIONALLY LEFT BLANK’;

- (d) point CAT.OP.MPA.151 is deleted;
- (e) point CAT.OP.MPA.175 (b)(7) is replaced by the following:
 - ‘(7) the provisions specified in the operations manual in respect of fuel/energy, oil, oxygen, minimum safe altitudes, aerodrome operating minima and availability of alternate aerodromes, where required, can be complied with for the planned flight;’;
- (f) the following point CAT.OP.MPA.177 is inserted:
 - ‘CAT.OP.MPA.177 Submission of the ATS flight plan
 - (a) If an air traffic services (ATS) flight plan is not submitted because it is not required by the rules of the air, adequate information shall be deposited in order to permit alerting services to be activated if required.
 - (b) When operating from a site where it is impossible to submit an ATS flight plan, the ATS flight plan shall be transmitted as soon as possible after take-off by the commander or the operator.’;
- (g) point CAT.OP.MPA.180 is replaced by the following:
 - ‘CAT.OP.MPA.180 Fuel/energy scheme – aeroplanes
 - (a) The operator shall establish, implement, and maintain a fuel/energy scheme that:
 - (1) is appropriate for the type(s) of operation performed;
 - (2) corresponds to the capability of the operator to support its implementation; and
 - (3) is either:
 - (i) a basic fuel/energy scheme, which shall form the basis for a basic fuel/energy scheme with variations and an individual fuel/energy scheme; the basic fuel/energy scheme derives from a large-scale analysis of safety and operational data from previous performance and experience of the industry, applying scientific principles; the basic fuel/energy scheme shall ensure, in this order, a safe, effective, and efficient operation of the aircraft; or
 - (ii) a basic fuel/energy scheme with variations, which is a basic fuel/energy scheme where the analysis referred to in point (i) is used to establish a variation to the basic fuel/energy scheme that ensures, in this order, a safe, effective, and efficient operation of the aircraft; or
 - (iii) an individual fuel/energy scheme, which derives from a comparative analysis of the operator’s safety and operational data, applying scientific principles; the analysis is used to establish a fuel/energy scheme with a higher or equivalent level of safety to that of the basic fuel/energy scheme that ensures, in this order, a safe, effective, and efficient operation of the aircraft.
 - (b) All fuel/energy schemes shall comprise:
 - (1) a fuel/energy planning and in-flight re-planning policy;
 - (2) an aerodrome selection policy; and
 - (3) an in-flight fuel/energy management policy.
 - (c) The fuel/energy scheme and any change to it shall require prior approval by the competent authority.
 - (d) When the operator intends to apply for an individual fuel/energy scheme, it shall:
 - (1) establish a baseline safety performance of its current fuel/energy scheme;
 - (2) demonstrate its capability to support the implementation of the proposed individual fuel/energy scheme, including the capability to exercise adequate operational control and to ensure exchange of the relevant safety information between the operational control personnel and the flight crew; and
 - (3) make a safety risk assessment that demonstrates how an equivalent level of safety to that of the current fuel/energy scheme is achieved.’;

- (h) point CAT.OP.MPA.181 is replaced by the following:
'CAT.OP.MPA.181 Fuel/energy scheme – fuel/energy planning and in-flight re-planning policy – aeroplanes
- (a) The operator shall:
- (1) establish a fuel/energy planning and in-flight re-planning policy as part of the fuel/energy scheme;
 - (2) ensure that the aeroplane carries a sufficient amount of usable fuel/energy to safely complete the planned flight and to allow for deviations from the planned operation;
 - (3) develop procedures for the fuel/energy planning and in-flight re-planning policy that shall be contained in the operations manual.
 - (4) ensure that the fuel/energy planning of the flight is based on:
 - (i) current aircraft-specific data derived from a fuel/energy consumption monitoring system or, if not available;
 - (ii) data provided by the aeroplane manufacturer.
- (b) The operator shall ensure that the planning of flights includes the operating conditions under which the flight is to be conducted; the operating conditions shall include at least:
- (1) aircraft fuel/energy consumption data;
 - (2) anticipated masses;
 - (3) anticipated meteorological conditions;
 - (4) the effects of deferred maintenance items and/or of configuration deviations;
 - (5) the expected departure and arrival routing and runways; and
 - (6) anticipated delays.
- (c) The operator shall ensure that the pre-flight calculation of the usable fuel/energy that is required for a flight includes:
- (1) taxi fuel/energy that shall not be less than the amount expected to be used prior to take-off;
 - (2) trip fuel/energy that shall be the amount of fuel/energy that is required to enable the aeroplane to fly from take-off, or from the point of in-flight re-planning, to landing at the destination aerodrome;
 - (3) contingency fuel/energy that shall be the amount of fuel/energy required to compensate for unforeseen factors;
 - (4) destination alternate fuel/energy:
 - (i) when a flight is operated with at least one destination alternate aerodrome, it shall be the amount of fuel/energy required to fly from the destination aerodrome to the destination alternate aerodrome; or
 - (ii) when a flight is operated with no destination alternate aerodrome, it shall be the amount of fuel/energy required to hold at the destination aerodrome, while enabling the aeroplane to perform a safe landing, and to allow for deviations from the planned operation; as a minimum, this amount shall be 15-minute fuel/energy at holding speed at 1 500 ft (450 m) above the aerodrome elevation in standard conditions, calculated according to the estimated aeroplane mass on arrival at the destination aerodrome;
 - (5) final reserve fuel/energy that shall be the amount of fuel/energy that is calculated at holding speed at 1 500 ft (450 m) above the aerodrome elevation in standard conditions according to the aeroplane estimated mass on arrival at the destination alternate aerodrome, or destination aerodrome when no destination alternate aerodrome is required, and shall not be less than:
 - (i) for aeroplanes with reciprocating engines, the fuel/energy to fly for 45 minutes; or
 - (ii) for turbine-engined aeroplanes, the fuel/energy to fly for 30 minutes;

- (6) additional fuel/energy, if required by the type of operation; it shall be the amount of fuel/energy to enable the aeroplane to land at a fuel/energy en route alternate aerodrome (fuel/energy ERA aerodrome critical scenario) in the event of an aircraft failure that significantly increases the fuel/energy consumption at the most critical point along the route; this additional fuel/energy is required only if the minimum amount of fuel/energy that is calculated according to points (c)(2) to (c)(5) is not sufficient for such an event;
 - (7) extra fuel/energy to take into account anticipated delays or specific operational constraints; and
 - (8) discretionary fuel/energy, if required by the commander.
- (d) The operator shall ensure that in-flight re-planning procedures for calculating the usable fuel/energy that is required when a flight proceeds along a route or to a destination aerodrome other than the ones originally planned include points (c)(2) to (c)(7).;
- (i) point CAT.OP.MPA.182 is replaced by the following:

‘CAT.OP.MPA.182 Fuel/energy scheme – aerodrome selection policy – aeroplanes

 - (a) At the planning stage, the operator shall ensure that once the flight has commenced, there is reasonable certainty that an aerodrome where a safe landing can be made will be available at the estimated time of use of that aerodrome.
 - (b) At the planning stage, to allow for a safe landing in case of an abnormal or emergency situation after take-off, the operator shall select and specify in the operational flight plan a take-off alternate aerodrome if either:
 - (1) the meteorological conditions at the aerodrome of departure are below the operator’s established aerodrome landing minima for that operation; or
 - (2) it would be impossible to return to the aerodrome of departure for other reasons.
 - (c) The take-off alternate aerodrome shall be located within a distance from the departure aerodrome that minimises the risk of exposure to potential abnormal or emergency situations. In selecting the take-off alternate aerodrome, the operator shall consider at least the following:
 - (1) actual and forecast meteorological conditions;
 - (2) availability and quality of the aerodrome infrastructure;
 - (3) navigation and landing capabilities of the aircraft in abnormal or emergency conditions, taking into account the redundancy of critical systems; and
 - (4) approvals held (e.g. extended range operations with two-engined aeroplanes (ETOPS), low visibility operation (LVO), etc.).
 - (d) At the planning stage, for each instrument flight rules (IFR) flight, the operator shall select and specify in the operational and air traffic services (ATS) flight plans one or more aerodromes so that two safe-landing options are available during normal operation when:
 - (1) reaching the destination aerodrome; or
 - (2) reaching the point of no return, to any available fuel/energy ERA aerodrome during isolated aerodrome operations; a flight to an isolated aerodrome shall not be continued past the point of no return unless a current assessment of meteorological conditions, traffic, and other operational conditions indicates that a safe landing can be made at the destination aerodrome at the estimated time of use.

The operator shall obtain prior approval from the competent authority for the use of an isolated aerodrome as destination aerodrome.
 - (e) The operator shall provide appropriate safety margins to flight planning to take into account a possible deterioration of the available forecast meteorological conditions at the estimated time of landing.
 - (f) For each IFR flight, the operator shall ensure that sufficient means are available to navigate to and land at the destination aerodrome or at any destination alternate aerodrome in the event of loss of capability for the intended approach and landing operation.’

- (j) point CAT.OP.MPA.185 is replaced by the following:
'CAT.OP.MPA.185 Fuel/energy scheme – in-flight fuel/energy management policy – aeroplanes
- (a) The operator shall establish procedures for in-flight fuel/energy management that ensure:
- (1) continual validation of the assumptions made during the planning stage (pre-flight or in-flight re-planning, or both);
 - (2) re-analysis and adjustment, if necessary;
 - (3) that the amount of usable fuel/energy remaining on board is protected and not less than the fuel/energy that is required to proceed to an aerodrome where a safe landing can be made; and
 - (4) relevant fuel/energy data for the purpose of points (1), (2), and (3) shall be recorded.
- (b) The operator shall have procedures in place to require the commander to obtain delay information from a reliable source when unforeseen circumstances may result in landing at the destination aerodrome with less than the final reserve fuel/energy plus any:
- (1) fuel/energy to proceed to an alternate aerodrome, if required; or
 - (2) fuel/energy required to proceed to an isolated aerodrome.
- (c) The commander shall advise air traffic control (ATC) of a 'minimum fuel/energy' state by declaring 'MINIMUM FUEL' when the commander has:
- (1) committed to land at a specific aerodrome; and
 - (2) calculated that any change to the existing clearance to that aerodrome may result in landing with less than the planned final reserve fuel/energy.
- (d) The commander shall declare a situation of 'fuel/energy emergency' by broadcasting 'MAYDAY MAYDAY MAYDAY FUEL' when the usable fuel/energy that is calculated to be available upon landing at the nearest aerodrome where a safe landing can be made is less than the planned final reserve fuel/energy.';
- (k) point CAT.OP.MPA.186 is deleted;
- (l) point CAT.OP.MPA.190 is replaced by the following:
'CAT.OP.MPA.190 Fuel/energy scheme – helicopters
- (a) The operator shall establish, implement, and maintain a fuel/energy scheme that comprises:
- (1) a fuel/energy planning and in-flight re-planning policy; and
 - (2) an in-flight fuel/energy management policy.
- (b) The fuel/energy scheme shall:
- (1) be appropriate for the type(s) of operation performed; and
 - (2) correspond to the capability of the operator to support its implementation.
- (c) The fuel/energy scheme and any change to it shall require prior approval by the competent authority.';
- (m) the following points CAT.OP.MPA.191 and CAT.OP.MPA.192 are inserted:
'CAT.OP.MPA.191 Fuel/energy scheme – Fuel/energy planning and in-flight re-planning policy – helicopters
- (a) As part of the fuel/energy scheme, the operator shall establish a fuel/energy planning and in-flight re-planning policy to ensure that the aircraft carries a sufficient amount of usable fuel/energy to safely complete the planned flight and to allow for deviations from the planned operation.
- (b) The operator shall ensure that the fuel/energy planning of flights is based upon at least the following elements:
- (1) procedures contained in the operations manual as well as:
 - (i) current aircraft-specific data derived from a fuel/energy consumption monitoring system; or

- (ii) data provided by the aircraft manufacturer; and
- (2) the operating conditions under which the flight is to be conducted including:
 - (i) aircraft fuel/energy consumption data;
 - (ii) anticipated masses;
 - (iii) anticipated meteorological conditions;
 - (iv) the effects of deferred maintenance items or of configuration deviations, or both; and
 - (v) procedures and restrictions introduced by air navigation service providers.
- (c) The operator shall ensure that the pre-flight calculation of the usable fuel/energy that is required for a flight includes:
 - (1) taxi fuel/energy, which shall not be less than the amount expected to be used prior to take-off;
 - (2) trip fuel/energy;
 - (3) contingency fuel/energy;
 - (4) destination alternate fuel/energy if a destination alternate aerodrome is required;
 - (5) final reserve fuel/energy, which shall not be less than:
 - (i) if flying under visual flight rules (VFR) and navigating by day with reference to visual landmarks, 20-minute fuel/energy at best-range speed; or
 - (ii) if flying under VFR and navigating by means other than by reference to visual landmarks or at night, 30-minute fuel/energy at best-range speed; or
 - (iii) if flying under instrument flight rules (IFR), 30-minute fuel/energy at holding speed at 1 500 ft (450 m) above the aerodrome elevation in standard conditions, calculated according to the helicopter estimated mass on arrival at the destination alternate aerodrome or at the destination aerodrome when no destination alternate aerodrome is required;
 - (6) extra fuel/energy, to take into account anticipated delays or specific operational constraints; and
 - (7) discretionary fuel/energy, if required by the commander.
- (d) The operator shall ensure that if a flight has to proceed along a route or to a destination aerodrome other than the ones originally planned, in-flight re-planning procedures for calculating the required usable fuel/energy include:
 - (1) trip fuel/energy for the remainder of the flight;
 - (2) reserve fuel/energy consisting of:
 - (i) contingency fuel/energy;
 - (ii) alternate fuel/energy if a destination alternate aerodrome is required;
 - (iii) final reserve fuel/energy; and
 - (iv) additional fuel/energy, if required by the type of operation;
 - (3) extra fuel/energy, to take into account anticipated delays or specific operational constraints; and
 - (4) discretionary fuel/energy, if required by the commander.
- (e) As an alternative to points (b) to (d), for helicopters with a maximum certified take-off mass (MCTOM) of 3 175 kg or less, flying by day and over routes navigated by reference to visual landmarks, or for local helicopter operations (LHO), the fuel/energy policy shall ensure that on completion of the flight, or series of flights, the final reserve fuel/energy is sufficient for:
 - (1) 30-minute flying time at best-range speed; or
 - (2) 20-minute flying time at best-range speed, if operating within an area providing continuous and suitable operating sites'.

CAT.OP.MPA.192 Selection of aerodromes and operating sites – helicopters

- (a) For flights under instrument meteorological conditions (IMC), the operator shall select a take-off alternate aerodrome within one-hour flying time at normal cruising speed if it is not possible to return to the site of departure for meteorological reasons.
 - (b) At the planning stage, for each instrument flight rules (IFR) flight, the operator shall select and specify in the operational and air traffic services (ATS) flight plans one or more aerodromes or operating sites so that two safe-landing options are available during normal operation, except as provided for under point SPA.HOFO.120 (b).
 - (c) The operator shall apply appropriate safety margins to flight planning to take into account a possible deterioration of the available forecast meteorological conditions at the estimated time of landing.
 - (d) For each IFR flight, the operator shall ensure that sufficient means are available to navigate to and land at the destination aerodrome or at any destination alternate aerodrome in the event of loss of capability for the intended approach and landing operation.’;
- (n) point CAT.OP.MPA.195 is replaced by the following:
- ‘CAT.OP.MPA.195 Fuel/energy scheme – in-flight fuel/energy management policy – helicopters
- (a) The operator shall establish procedures to ensure that in-flight fuel/energy checks and fuel/energy management are performed.
 - (b) The commander shall monitor the amount of usable fuel/energy remaining on board to ensure that it is protected and not less than the fuel/energy that is required to proceed to an aerodrome or operating site where a safe landing can be made.
 - (c) The commander shall advise air traffic control (ATC) of a ‘minimum fuel/energy’ state by declaring ‘MINIMUM FUEL’ when the commander has:
 - (1) committed to land at an aerodrome or operating site; and
 - (2) calculated that any change to the existing clearance to that aerodrome or operating site, or other air traffic delays, may result in landing with less than the planned final reserve fuel/energy.
 - (d) The commander shall declare a situation of ‘fuel/energy emergency’ by broadcasting ‘MAYDAY MAYDAY MAYDAY FUEL’ when the usable fuel/energy estimated to be available upon landing at the nearest aerodrome or operating site where a safe landing can be made is less than the planned final reserve fuel/energy.’;
- (o) the following point CAT.OP.MPA.200 is replaced:
- ‘CAT.OP.MPA.200 Special refuelling or defuelling of the aircraft
- (a) Special refuelling or defuelling shall only be conducted if the operator:
 - (1) has performed a risk assessment;
 - (2) has developed procedures; and
 - (3) has established a training programme for its personnel involved in such operations.
 - (b) Special refuelling or defuelling applies to:
 - (1) refuelling with an engine running or rotors turning;
 - (2) refuelling/defuelling with passengers embarking, on board, or disembarking; and
 - (3) refuelling/defuelling with wide-cut fuel.
 - (c) For aeroplanes, any special refuelling or defuelling procedures and any change to them shall require prior approval by the competent authority.
 - (d) For helicopters, refuelling procedures with rotors turning and any change to them shall require prior approval by the competent authority.’;

- (p) point CAT.OP.MPA.245 (a)(1) is replaced by the following:
'(1) commence the flight; or';
 - (q) point CAT.OP.MPA.246 (a) is replaced by the following:
'(a) the decision point when using the reduced contingency fuel/energy procedure; or';
 - (r) point CAT.OP.MPA.260 is replaced by the following:
'CAT.OP.MPA.260 Fuel/energy and oil supply
The commander shall only commence a flight or continue in the event of in-flight re-planning, when satisfied that the aircraft carries at least the planned amount of usable fuel/energy and oil to safely complete the flight, taking into account the expected operating conditions.';
 - (s) point CAT.OP.MPA.280 'In-flight fuel management – aeroplanes' is replaced by the following:
'CAT.OP.MPA.280
[INTENTIONALLY LEFT BLANK].';
 - (t) point CAT.OP.MPA.281 is deleted;
 - (u) point CAT.POL.A.220 (f) is replaced by the following:
'(f) The expected mass of the aeroplane at the point where the two engines are assumed to fail shall not be less than that which would include sufficient fuel/energy to proceed to an aerodrome where the landing is assumed to be made, and to arrive there at an altitude of at least 1 500 ft (450 m) directly over the landing area, and thereafter, to fly for 15 minutes at cruising power or thrust, as appropriate.';
 - (v) point CAT.POL.A.420 (d) is replaced by the following:
'(d) The expected mass of the aeroplane at the point where the two engines are assumed to fail shall not be less than that which would include sufficient fuel/energy to proceed to an aerodrome where the landing is assumed to be made, and to arrive there at an altitude of at least 1 500 ft (450 m) directly over the landing area, and thereafter, to fly for 15 minutes at cruising power or thrust, as appropriate.';
 - (w) point CAT.IDE.A.195 (e) is replaced by the following:
'(e) The requirements applicable to the start and stop logic of the data link recorder are the same as the requirements applicable to the start and stop logic of the cockpit voice recorder (CVR) that are contained in point CAT.IDE.A.185.';
- (5) Annex V is amended as follows:
- (a) point SPA.HEMS.150 is replaced by the following:
'SPA.HEMS.150 Fuel/energy supply – alleviation
As an alternative to points CAT.OP.MPA.191 (b), (c), and (d), when the helicopter emergency medical services (HEMS) mission is conducted under visual flight rules (VFR) within a local and defined geographical area, the fuel/energy policy shall ensure that on completion of the mission, the final reserve fuel/energy is sufficient for:
(a) 30-minute flying time at best-range speed; or
(b) 20-minute flying time at best-range speed by day, when operating within an area providing continuous and suitable operating sites.';
 - (b) point SPA.HEMS.155 is replaced by the following:
'SPA.HEMS.155 Refuelling with passengers on board
A refuelling procedure with either rotors stopped or rotors turning shall be provided in accordance with point CAT.OP.MPA.200 'Special refuelling or defuelling of the aircraft.';
 - (c) point SPA.HOFO.120 (a) is replaced by the following:
'(a) *Onshore destination alternate aerodrome.* By way of derogation from points CAT.OP.MPA.192, NCC.OP.152, and SPO.OP.151, the pilot-in-command/commander does not need to specify a destination alternate aerodrome in the operational flight plan when conducting flights from an offshore location to a land aerodrome if either:
(1) the destination aerodrome is defined as a coastal aerodrome, or

- (2) the following criteria are met:
- (i) the destination aerodrome has a published instrument approach;
 - (ii) the flight time is less than 3 hours; and
 - (iii) the published weather forecast valid from 1 hour prior and 1 hour subsequent to the expected landing time specifies that:
 - (A) the cloud base is at least 700 feet above the minima associated with the instrument approach, or 1 000 feet above the destination aerodrome, whichever is higher; and
 - (B) visibility is at least 2 500 meters.;
- (d) point SPA.SET-IMC.110 (l) is replaced by the following:
- ‘(l) an emergency engine power control device that permits continuing operation of the engine at a sufficient power range to safely complete the flight in the event of any reasonably probable failure of the fuel/energy control unit.’
- (6) Annex VI is amended as follows:
- (a) point NCC.OP.105 is replaced by the following:
- ‘NCC.OP.105 Specification of isolated aerodromes – aeroplanes
- For the selection of alternate aerodromes and the fuel/energy planning and in-flight re-planning policy, the operator shall not consider an aerodrome as an isolated aerodrome unless the flying time to the nearest weather-permissible destination alternate aerodrome is more than:
- (a) for aeroplanes with reciprocating engines, 60 minutes; or
 - (b) for turbine-engined aeroplanes, 90 minutes.;
- (b) points NCC.OP.130 and NCC.OP.131 are replaced by the following:
- ‘NCC.OP.130 Fuel/energy scheme – aeroplanes and helicopters
- (a) The operator shall establish, implement, and maintain a fuel/energy scheme that comprises:
- (1) a fuel/energy planning and in-flight re-planning policy; and
 - (2) an in-flight fuel/energy management policy.
- (b) The fuel/energy scheme shall:
- (1) be appropriate for the type(s) of operation performed; and
 - (2) correspond to the capability of the operator to support its implementation.
- NCC.OP.131 Fuel/energy scheme – fuel/energy planning and in-flight re-planning policy – aeroplanes and helicopters
- (a) As part of the fuel/energy scheme, the operator shall establish a fuel/energy planning and in-flight re-planning policy to ensure that the aircraft carries a sufficient amount of usable fuel/energy to safely complete the planned flight and to allow for deviations from the planned operation.
- (b) The operator shall ensure that the fuel/energy planning of flights is based upon at least the following elements:
- (1) procedures contained in the operations manual as well as:
 - (i) current aircraft-specific data derived from a fuel/energy consumption monitoring system, or, if not available;
 - (ii) data provided by the aircraft manufacturer; and
 - (2) the operating conditions under which the flight is to be conducted including:
 - (i) aircraft fuel/energy consumption data;
 - (ii) anticipated masses;
 - (iii) anticipated meteorological conditions;

- (iv) the effects of deferred maintenance items or configuration deviations, or both; and
 - (v) anticipated delays.
- (c) For aeroplanes, the operator shall ensure that the pre-flight calculation of the usable fuel/energy that is required for a flight includes:
 - (1) taxi fuel/energy that shall not be less than the amount expected to be used prior to take-off;
 - (2) trip fuel/energy that shall be the amount of fuel/energy that is required to enable the aeroplane to fly from take-off, or from the point of in-flight re-planning, to landing at the destination aerodrome;
 - (3) contingency fuel/energy that shall be the amount of fuel/energy required to compensate for unforeseen factors;
 - (4) destination alternate fuel/energy:
 - (i) when a flight is operated with at least one destination alternate aerodrome, it shall be the amount of fuel/energy required to fly from the destination aerodrome to the destination alternate aerodrome; or
 - (ii) when a flight is operated with no destination alternate aerodrome, it shall be the amount of fuel/energy required to hold at the destination aerodrome to compensate for the lack of a destination alternate aerodrome;
 - (5) final reserve fuel/energy that shall be the amount of fuel/energy that is calculated at holding speed at 1 500 ft (450 m) above the aerodrome elevation in standard conditions according to the aircraft estimated mass on arrival at the destination alternate aerodrome, or destination aerodrome when no destination alternate aerodrome is required, and shall not be less than:
 - (i) for aeroplanes with reciprocating engines on visual flight rules (VFR) flights by night and instrument flight rules (IFR) flights, the fuel/energy to fly for 45 minutes; or
 - (ii) for aeroplanes with reciprocating engines on VFR flights by day, the fuel/energy to fly for 30 minutes;
 - (iii) for turbine-engined aeroplanes, the fuel/energy to fly for 30 minutes;
 - (6) additional fuel/energy, if required by the type of operation; it shall be the amount of fuel/energy to enable the aeroplane to perform a safe landing at a fuel/energy en route alternate aerodrome (fuel/energy ERA aerodrome critical scenario) in the event of an engine failure or loss of pressurisation, whichever requires the greater amount of fuel/energy, based on the assumption that such a failure occurs at the most critical point along the route; this additional fuel/energy is required only if the minimum amount of fuel/energy that is calculated according to points (c)(2) to (c)(5) is not sufficient for such an event;
 - (7) extra fuel/energy to take into account anticipated delays or specific operational constraints; and
 - (8) discretionary fuel/energy, if required by the commander.
- (d) For helicopters, the operator shall ensure that the pre-flight calculation of the usable fuel/energy that is required for a flight includes all of the following:
 - (1) fuel/energy to fly to the aerodrome or operating site of intended landing;
 - (2) if a destination alternate is required, destination alternate fuel/energy, which shall be the amount of fuel/energy that is required to execute a missed approach at the aerodrome or operating site of intended landing, and thereafter, to fly to the specified destination alternate, approach and land; and
 - (3) final reserve fuel/energy, which shall not be less than:
 - (i) for flights under VFR, fuel/energy to fly for at least 20 minutes at best-range speed; or
 - (ii) for IFR flights, fuel/energy to fly for at least 30 minutes at holding speed at 450 m (1 500 ft) above the aerodrome or operating site of intended landing or destination alternate in standard temperature conditions.

- (e) The operator shall ensure that if a flight has to proceed to a destination aerodrome other than the one originally planned, in-flight re-planning procedures for calculating the required usable fuel/energy are available and comply with points (c)(2) to (c)(7) for aeroplanes, and point (d) for helicopters.
- (f) The pilot in command shall only commence a flight or continue in the event of in-flight re-planning, when satisfied that the aircraft carries at least the planned amount of usable fuel/energy and oil to safely complete the flight.’;
- (c) point NCC.OP.151 (b) is replaced by the following:
 - ‘(b) the place of intended landing is designated as an isolated aerodrome and:
 - (1) an instrument approach procedure is prescribed for the aerodrome of intended landing; and
 - (2) available current meteorological information indicates that the following meteorological conditions will exist from 2 hours before to 2 hours after the estimated time of arrival:
 - (i) a cloud base of at least 300 m (1 000 ft) above the minimum associated with the instrument approach procedure; and
 - (ii) visibility of at least 5,5 km or of 4 km more than the minimum associated with the procedure.’;
- (d) point NCC.OP.155 (b) is replaced by the following:
 - ‘(b) For all other types of fuel/energy, necessary precautions shall be taken and the aircraft shall be properly manned by qualified personnel ready to initiate and direct an evacuation of the aircraft by the most practical and expeditious means available.’;
- (e) the following point NCC.OP.157 is inserted:
 - ‘NCC.OP.157 Refuelling with engine(s) and/or rotors turning – helicopters
 - (a) Refuelling with engine(s) and/or rotors turning shall only be conducted:
 - (1) with no passengers embarking or disembarking;
 - (2) if the operator of the aerodrome/operating site allows such operations;
 - (3) in accordance with any specific procedures and limitations in the aircraft flight manual (AFM);
 - (4) with JET A or JET A-1 fuel types; and
 - (5) in the presence of the appropriate rescue and firefighting (RFF) facilities or equipment.
 - (b) The operator shall assess the risks associated with refuelling with engine(s) and/or rotors turning.
 - (c) The operator shall establish appropriate procedures to be followed by all involved personnel, such as crew members and ground operations personnel.
 - (d) The operator shall train its crew members and ensure that the involved ground operations personnel is trained appropriately.
 - (e) The operator shall ensure that the helicopter refuelling procedure with engine(s) and/or rotors turning are specified in the operations manual. This procedure and any change thereto shall require prior approval by the competent authority.’;
- (f) point NCC.OP.205 is replaced by the following:
 - ‘NCC.OP.205 Fuel/energy scheme – in-flight fuel/energy management policy
 - (a) The operator shall establish procedures to ensure that in-flight fuel/energy checks and fuel/energy management are performed.
 - (b) The pilot-in-command shall monitor the amount of usable fuel/energy remaining on board to ensure that it is protected and not less than the fuel/energy that is required to proceed to an aerodrome or operating site where a safe landing can be made.
 - (c) The pilot-in-command shall advise air traffic control (ATC) of a ‘minimum fuel/energy’ state by declaring ‘MINIMUM FUEL’ when the pilot-in-command has:
 - (1) committed to land at a specific aerodrome or operating site; and

- (2) calculated that any change to the existing clearance to that aerodrome or operating site, or other air traffic delays, may result in landing with less than the planned final reserve fuel/energy.
 - (d) The pilot-in-command shall declare a situation of 'fuel/energy emergency' by broadcasting 'MAYDAY MAYDAY MAYDAY FUEL' when the usable fuel/energy estimated to be available upon landing at the nearest aerodrome or operating site where a safe landing can be made is less than the planned final reserve fuel/energy.;
- (g) in point NCC.POL.110 (a), points (6), (7), (8) and (9) are replaced by the following:
 - '(6) mass of the fuel/energy at take-off and mass of trip fuel/energy;
 - (7) mass of consumables other than fuel/energy, if applicable;
 - (8) load components including passengers, baggage, freight, and ballast;
 - (9) take-off mass, landing mass, and zero fuel/energy mass.;
- (7) Annex VII is amended as follows:
 - (a) point NCO.OP.105 is replaced by the following:

NCO.OP.105 Specification of isolated aerodromes – aeroplanes

'For the selection of alternate aerodromes and the fuel/energy supply, the pilot-in-command shall not consider an aerodrome as an isolated aerodrome unless the flying time to the nearest weather-permissible destination alternate aerodrome is more than:

 - (a) for aeroplanes with reciprocating engines, 60 minutes; or
 - (b) for turbine-engined aeroplanes, 90 minutes.;
 - (b) point NCO.OP.125 is replaced by the following:

NCO.OP.125 Fuel/energy and oil supply – aeroplanes and helicopters

 - (a) The pilot-in-command shall ensure that the quantity of fuel/energy and oil that is carried on board is sufficient, taking into account the meteorological conditions, any element affecting the performance of the aircraft, any delays that are expected in flight, and any contingencies that may reasonably be expected to affect the flight.
 - (b) The pilot-in-command shall plan a quantity of fuel/energy to be protected as final reserve fuel/energy to ensure a safe landing. The pilot-in-command shall take into account all of the following, and in the following order of priority, to determine the quantity of the final reserve fuel/energy:
 - (1) the severity of the hazard to persons or property that may result from an emergency landing after fuel/energy starvation; and
 - (2) the likelihood of unexpected circumstances that the final reserve fuel/energy may no longer be protected.
 - (c) The pilot-in-command shall commence a flight only if the aircraft carries sufficient fuel/energy and oil:
 - (1) when no destination alternate is required, to fly to the aerodrome or operating site of intended landing, plus the final reserve fuel/energy; or
 - (2) when a destination alternate is required, to fly to the aerodrome or operating site of intended landing, and thereafter, to an alternate aerodrome, plus the final reserve fuel/energy.;
 - (c) point NCO.OP.126 'is deleted;
 - (d) point NCO.OP.145 (b) is replaced by the following:

'(b) For all other types of fuel/energy, the aircraft shall not be refuelled when passengers are embarking, on board or disembarking, unless it is attended by the pilot-in-command or other qualified personnel ready to initiate and direct an evacuation of the aircraft by the most practical and expeditious means available.;
 - (e) the following point NCO.OP.147 is inserted:

NCO.OP.147 Refuelling with engine(s)and/or rotors turning – helicopters

Refuelling with engine(s) and/or rotors turning shall only be conducted if all those conditions are met simultaneously:

- (a) if it is not practical to shut down or restart the engine;
 - (b) in accordance with any specific procedures and limitations in the aircraft flight manual (AFM);
 - (c) with JET A or JET A-1 fuel types;
 - (d) with no passengers or task specialists on board, embarking or disembarking;
 - (e) if the operator of the aerodrome or operating site allows such operations;
 - (f) in the presence of the appropriate rescue and firefighting (RFF) facilities or equipment; and
 - (g) in accordance with a checklist that shall contain:
 - (1) normal and contingency procedures;
 - (2) the required equipment;
 - (3) any limitations; and
 - (4) responsibilities and duties of the pilot-in-command and, if applicable, crew members and task specialists.’;
- (f) point NCO.OP.185 is replaced by the following:
‘NCO.OP.185 In-flight fuel/energy management
- (a) The pilot-in-command shall monitor the amount of usable fuel/energy remaining on board to ensure that it is protected and not less than the fuel/energy that is required to proceed to an aerodrome or operating site where a safe landing can be made.
 - (b) The pilot-in-command of a controlled flight shall advise air traffic control (ATC) of a ‘minimum fuel/energy’ state by declaring ‘MINIMUM FUEL’ when the pilot-in-command has:
 - (1) committed to land at a specific aerodrome or operating site; and
 - (2) calculated that any change to the existing clearance to that aerodrome or operating site, or other air traffic delays, may result in landing with less than the planned final reserve fuel/energy.
 - (c) The pilot-in-command of a controlled flight shall declare a situation of ‘fuel/energy emergency’ by broadcasting ‘MAYDAY MAYDAY MAYDAY FUEL’ when the usable fuel/energy estimated to be available upon landing at the nearest aerodrome or operating site where a safe landing can be made is less than the planned final reserve fuel/energy.’;
- (g) points NCO.SPEC.135 and NCO.SPEC.140 are deleted;
- (8) Annex VIII is amended as follows:
- (a) point SPO.OP.105 is replaced by the following:
‘SPO.OP.105 Specification of isolated aerodromes – aeroplanes

For the selection of alternate aerodromes and the fuel/energy planning and in-flight re-planning policy, the operator shall not consider an aerodrome as an isolated aerodrome unless the flying time to the nearest weather-permissible destination alternate aerodrome is more than:

 - (a) for aeroplanes with reciprocating engines, 60 minutes; or
 - (b) for turbine-engined aeroplanes, 90 minutes.’; - (b) points SPO.OP.130 and SPO.OP.131 are replaced by the following:
‘SPO.OP.130 Fuel/energy scheme – aeroplanes and helicopters
 - (a) The operator shall establish, implement, and maintain a fuel/energy scheme that comprises:
 - (1) a fuel/energy planning and in-flight re-planning policy; and
 - (2) an in-flight fuel/energy management policy.

(b) The fuel/energy scheme shall:

- (1) be appropriate for the type(s) of operation performed; and
- (2) correspond to the capability of the operator to support its implementation.

SPO.OP.131 Fuel/energy scheme – fuel/energy planning and in-flight re-planning policy – aeroplanes and helicopters

- (a) As part of the fuel/energy scheme, the operator shall establish a fuel/energy planning and in-flight re-planning policy to ensure that the aircraft carries a sufficient amount of usable fuel/energy to safely complete the planned flight and to allow for deviations from the planned operation.
- (b) The operator shall ensure that the fuel/energy planning of flights is based upon at least the following elements:
 - (1) procedures contained in the operations manual as well as:
 - (i) current aircraft-specific data derived from a fuel/energy consumption monitoring system or, if not available;
 - (ii) data provided by the aircraft manufacturer; and
 - (2) the operating conditions under which the flight is to be conducted including:
 - (i) aircraft fuel/energy consumption data;
 - (ii) anticipated masses;
 - (iii) anticipated meteorological conditions;
 - (iv) the effects of deferred maintenance items and/or configuration deviations; and
 - (v) anticipated delays.
- (c) For aeroplanes, the operator shall ensure that the pre-flight calculation of the usable fuel/energy that is required for a flight includes:
 - (1) taxi fuel/energy that shall not be less than the amount expected to be used prior to take-off;
 - (2) trip fuel/energy that shall be the amount of fuel/energy that is required to enable the aeroplane to fly from take-off, or from the point of in-flight re-planning, to landing at the destination aerodrome;
 - (3) contingency fuel/energy that shall be the amount of fuel/energy required to compensate for unforeseen factors;
 - (4) destination alternate fuel/energy
 - (i) when a flight is operated with at least one destination alternate aerodrome, it shall be the amount of fuel/energy required to fly from the destination aerodrome to the destination alternate aerodrome; or
 - (ii) when a flight is operated with no destination alternate aerodrome, it shall be the amount of fuel/energy required to hold at the destination aerodrome to compensate for the lack of a destination alternate aerodrome;
 - (5) final reserve fuel/energy that shall be protected to ensure a safe landing; the operator shall take into account all of the following, and in the following order of priority, to determine the quantity of the final reserve fuel/energy:
 - (i) the severity of the hazard to persons or property that may result from an emergency landing after fuel/energy starvation;
 - (ii) the likelihood of unexpected circumstances that the final reserve fuel/energy may no longer be protected;
 - (6) additional fuel/energy, if required by the type of operation; it shall be the amount of fuel/energy to enable the aeroplane to perform a safe landing at a fuel/energy en route alternate aerodrome (fuel/energy ERA aerodrome critical scenario) in the event of an engine failure or loss of pressurisation, whichever requires the greater amount of fuel/energy, based on the assumption that such a failure occurs at the most critical point along the route; this additional fuel/energy is required only if the minimum amount of fuel/energy that is calculated according to points (c)(2) to (c)(5) is not sufficient for such an event;

- (7) extra fuel/energy to take into account anticipated delays or specific operational constraints; and
- (8) discretionary fuel/energy, if required by the pilot-in-command.
- (d) For helicopters, the operator shall ensure that the pre-flight calculation of the usable fuel/energy that is required for a flight includes all of the following:
 - (1) fuel/energy to fly to the aerodrome or operating site of intended landing;
 - (2) if a destination alternate is required, destination alternate fuel/energy, which shall be the amount of fuel/energy that is required to execute a missed approach at the aerodrome or operating site of intended landing, and thereafter, to fly to the specified destination alternate, approach and land; and
 - (3) final reserve fuel/energy, which shall be protected to ensure a safe landing; the operator shall take into account all of the following, and in the following order of priority, to determine the quantity of the final reserve fuel/energy:
 - (i) the severity of the hazard to persons or property that may result from an emergency landing after fuel/energy starvation; and
 - (ii) the likelihood of such unexpected circumstances that the final reserve fuel/energy may no longer be protected;
 - (4) extra fuel/energy to take into account anticipated delays or specific operational constraints; and
 - (5) discretionary fuel/energy, if required by the pilot-in-command.
 - (e) The operator shall ensure that, if a flight has to proceed to a destination aerodrome other than the one originally planned, in-flight re-planning procedures for calculating the required usable fuel/energy are available and comply with points (c)(2) to (c)(7) for aeroplanes, and point (d) for helicopters.
 - (f) The pilot in command shall only commence a flight or continue in the event of in-flight re-planning, when satisfied that the aircraft carries at least the planned amount of usable fuel/energy and oil to safely complete the flight.;
- (c) point SPO.OP.150 (b) is replaced by the following:
 - ‘(b) the place of intended landing is designated as an isolated aerodrome and:
 - (1) an instrument approach procedure is prescribed for the aerodrome of intended landing; and
 - (2) available current meteorological information indicates that both following meteorological conditions will exist from 2 hours before to 2 hours after the estimated time of arrival, or from the actual time of departure to 2 hours after the estimated time of arrival whichever is the shorter period:
 - (i) a cloud base of at least 300 m (1 000 ft) above the minimum associated with the instrument approach procedure;
 - (ii) visibility of at least 5,5 km or of 4 km more than the minimum associated with the procedure.;
- (d) point SPO.OP.155 (b) is replaced by the following:
 - ‘(b) For all other types of fuel/energy, necessary precautions shall be taken and the aircraft shall be properly manned by qualified personnel ready to initiate and direct an evacuation of the aircraft by the most practical and expeditious means available.;
- (e) the following point SPO.OP.157 is inserted:
 - ‘SPO.OP.157 Refuelling with engine(s) and/or rotors turning – helicopters
 - (a) Refuelling with engine(s) and/or rotors turning shall only be conducted:
 - (1) with no task specialists embarking or disembarking;
 - (2) if the operator of the aerodrome or operating site allows such operations;
 - (3) in accordance with any specific procedures and limitations in the aircraft flight manual (AFM);

- (4) with JET A or JET A-1 fuel types; and
 - (5) in the presence of the appropriate rescue and firefighting (RFF) facilities or equipment.
- (b) The operator shall assess the risks associated with refuelling with engine(s) and/or rotors turning.
- (c) The operator shall establish appropriate procedures to be followed by all involved personnel, such as crew members, task specialists, and ground operations personnel.
- (d) The operator shall ensure that its crew members, ground operations personnel, as well as any task specialist involved in the procedures, are appropriately trained.
- (e) The operator shall ensure that the helicopter refuelling procedures with engine(s) and/or rotors turning are specified in the operations manual.;
- (f) point SPO.OP.190 is replaced by the following:
 - 'SPO.OP.190 Fuel/energy scheme – in-flight fuel/energy management policy
 - (a) The operator of complex motor-powered aircraft shall establish procedures to ensure that in-flight fuel/energy checks and fuel/energy management are performed.
 - (b) The pilot-in-command shall monitor the amount of usable fuel/energy remaining on board to ensure that it is protected and not less than the fuel/energy that is required to proceed to an aerodrome or operating site where a safe landing can be made.
 - (c) The pilot-in-command shall advise air traffic control (ATC) of a 'minimum fuel/energy' state by declaring 'MINIMUM FUEL' when the pilot-in-command has:
 - (1) committed to land at a specific aerodrome or operating site; and
 - (2) calculated that any change to the existing clearance to that aerodrome or operating site, or other air traffic delays, may result in landing with less than the planned final reserve fuel/energy.
 - (d) The pilot-in-command shall declare a situation of 'fuel/energy emergency' by broadcasting 'MAYDAY MAYDAY MAYDAY FUEL' when the usable fuel/energy estimated to be available upon landing at the nearest aerodrome or operating site where a safe landing can be made is less than the planned final reserve fuel/energy.;
- (g) point SPO.POL.110 is replaced by the following:
 - 'SPO.POL.110 Mass and balance system – commercial operations with aeroplanes and helicopters and non-commercial operations with complex motor-powered aircraft
 - (a) The operator shall establish a mass and balance system to determine for each flight or series of flights the following:
 - (1) aircraft dry operating mass;
 - (2) mass of the traffic load;
 - (3) mass of the fuel/energy load;
 - (4) aircraft load and load distribution;
 - (5) take-off mass, landing mass, and zero fuel/energy mass; and
 - (6) applicable aircraft centre of gravity (CG) positions.
 - (b) The flight crew shall be provided with a means of replicating and verifying any mass and balance computation based on electronic calculations.
 - (c) The operator shall establish procedures to enable the pilot-in-command to determine the mass of the fuel/energy load by using the actual density or, if not known, the density calculated in accordance with a method specified in the operations manual.;
- (h) in point SPO.POL.115 (a), points (6), (7), (8) and (9) are replaced by the following:
 - '(6) mass of the fuel/energy at take-off and mass of trip fuel/energy;
 - (7) mass of consumables other than fuel/energy, if applicable;
 - (8) load components;

- (9) take-off mass, landing mass, and zero fuel/energy mass;;
 - (i) point SPO.IDE.H.146 (a)(1) is replaced by the following:
 - ‘(1) they are not within the scope of point SPO.IDE.H.145 (a);’.
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ANNEX II

In Annex I to Regulation (EU) No 965/2012, the following point (98b) is inserted:

‘(98b) “psychoactive substances” means alcohol, opioids, cannabinoids, sedatives and hypnotics, cocaine, other psychostimulants, hallucinogens, and volatile solvents, with the exception of caffeine and tobacco;’.

COMMISSION REGULATION (EU) 2021/1297

of 4 August 2021

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCA)s, their salts and C9-C14 PFCA-related substances

(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (ECHA), amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ⁽¹⁾, and in particular Article 68(1) thereof,

Whereas:

- (1) Linear and branched perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain ('C9-C14 PFCA)s, their salts and C9-C14 PFCA-related substances ⁽²⁾ currently mainly occur in the Union as unintended by-products during the manufacture of perfluorinated and polyfluorinated substances containing a carbon chain of less than nine carbon atoms, such as perfluorooctanoic acid (PFOA). Furthermore, it is possible that companies may consider the use of C9-C14 PFCA)s, their salts and C9-C14 PFCA-related substances as substitutes for PFOA, its salts and related substances in the future, especially after the Union Law restrictions on PFOA become applicable. Thus, it is necessary to prevent future possible manufacturing and use resulting in increasing releases into the environment.
- (2) On 17 December 2015 and 12 January 2017, respectively, two groups of C9-C14 PFCA)s, namely perfluorononan-1-oic acid ('PFNA') containing 9 carbon atoms in the chain, as well as its sodium and ammonium salts, and nonadecafluorodecanoic acid ('PFDA') containing 10 carbon atoms in the chain, as well as its sodium and ammonium salts, were included in the Candidate List of Substances of Very High Concern ('SVHC') to be potentially included in Annex XIV to Regulation (EC) No 1907/2006, as toxic for reproduction in accordance with Article 57(c) of that Regulation, and persistent, bioaccumulative and toxic ('PBT') substances, in accordance with Article 57(d) of that Regulation. Moreover, PFNA and PFDA, as well as their sodium and ammonium salts, are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽³⁾ as carcinogenic, category 2 and toxic to reproduction, category 1B. On 19 December 2012, hencosafluoroundecanoic acid ('PFUnDA') containing 11 carbon atoms in the chain, tricosafuorododecanoic acid ('PFDoDA') containing 12 carbon atoms in the chain, pentacosafuorotridecanoic acid ('PFTriDA') containing 13 carbon atoms in the chain and heptacosafuorotetradecanoic acid ('PFTDA') containing 14 carbon atoms in the chain were included in the Candidate List of SVHC, as very persistent and very bioaccumulative ('vPvB') substances, in accordance with Article 57(e) of Regulation (EC) No 1907/2006. C9-C14 PFCA-related substances are also to be regarded as PBT or vPvB substances, respectively, due to their transformation or degradation in the environment to C9-C14 PFCA)s.
- (3) On 6 October 2017, Germany and Sweden submitted to the European Chemicals Agency ('the Agency'), a dossier ⁽⁴⁾ pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier') proposing to restrict the manufacture and placing on the market of C9-C14 PFCA)s, their salts and C9-C14 PFCA-related substances on their own, and to restrict their use in the production of, and placing on the market in, other substances as a constituent, mixtures and articles or parts thereof. In order to reduce the release of those substances into the environment and to prevent them from being manufactured, placed on the market and used as substitutes for the substances

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ C9-C14 PFCA-related substances are substances that, based on their molecular structure are considered to have the potential to degrade or be transformed to C9-C14 PFCA)s.

⁽³⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽⁴⁾ <https://www.echa.europa.eu/documents/10162/2ec5dfdd-0e63-0b49-d756-4dc1bae7ec61>

restricted by entry 68 of Annex XVII to Regulation (EC) No 1907/2006 ⁽⁵⁾, Germany and Sweden proposed a concentration limit of 25 ppb for the sum of C9-C14 PFCAs and their salts and 260 ppb for the sum of C9-C14 PFCA-related substances. Exemptions were proposed by Germany and Sweden for C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances when they occur as unintended by-products during the manufacturing of fluorochemicals with a perfluoro carbon chain equal to or shorter than eight atoms or for use as transported isolated intermediates.

- (4) On 14 September 2018, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion concluding that, subject to modification of the scope and conditions proposed in the Annex XV dossier, a restriction on manufacture, use and placing on the market of C9-C14 PFCAs, their salts and related substances, is the most appropriate Union-wide measure to address the identified risks in terms of effectiveness in reducing those risks. RAC agreed with the concentration limits as proposed by Germany and Sweden. RAC agreed with the exemptions proposed by Germany and Sweden as the proposed restriction is not intended to prevent the manufacture of the fluorochemicals with six or less carbon atoms in the molecular chain. RAC recommended exempting for a limited period the use in the production of pressurised metered-dose inhalers that are critical for the treatment of lung diseases because of the low volumes in the order of few grams involved and the important medical use. RAC expressed the opinion to grant a time-limited exemption for semiconductors that contain low levels of C9-C14 PFCAs and for semi-finished and finished electronic equipment containing specialty semiconductors to be used as replacement parts for finished electronic equipment.
- (5) Furthermore, RAC recommended to apply to the restriction of C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances the same exemptions which apply to the PFOA restriction in entry 68 to Annex XVII of Regulation (EC) No 1907/2006.
- (6) On 29 November 2018, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion, indicating that the restriction proposed in the Annex XV dossier, as modified by RAC and SEAC, is the most appropriate Union-wide measure to address the identified risks in terms of its socioeconomic benefits and socioeconomic costs.
- (7) Based on the socioeconomic elements provided in the Annex XV dossier and submitted during the public consultations, SEAC agreed with the exemptions proposed in the Annex XV dossier and recommended by RAC. SEAC concurred with the proposed 18-month deferral of the restriction. In addition, SEAC suggested higher limit values for fluoropolymers that contain perfluoropropoxy-groups or perfluoromethoxy-groups and are used in specific product groups in order to allow their production. Nonetheless, the generic threshold of 25 ppb remains applicable to the final articles manufactured from those materials.
- (8) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1)(f) of Regulation (EC) No 1907/2006, was consulted during the restriction process and its opinion has been taken into account.
- (9) On 16 January 2019, the Agency submitted the opinions of the RAC and SEAC ⁽⁶⁾ to the Commission.
- (10) Regulation (EU) 2019/1021 of the European Parliament and of the Council ⁽⁷⁾ was amended in accordance with the decision adopted by the Conference of the Parties (SC-9/12) of the Stockholm Convention on Persistent Organic Pollutants for PFOA ⁽⁸⁾, which contains some but not all the derogations included in entry 68 of Annex XVII of Regulation (EC) No 1907/2006. Entry 68 of that Annex was effectively replaced by the abovementioned amendment of Regulation (EU) 2019/1021. The exemptions which apply to the use of PFOA, its salts and PFOA-related compounds in the amendment of Regulation (EU) 2019/1021 should also apply to C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances under the same conditions because of the manufacturing process of fluorochemicals in which both group of substances are present as impurities.

⁽⁵⁾ Commission Regulation (EU) 2017/1000 of 13 June 2017 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (OJ L 150, 14.6.2017, p. 14).

⁽⁶⁾ https://echa.europa.eu/documents/10162/13641/rest_pfcas_compiled_racseac_opi_en.pdf/b06db225-3995-13fd-d89a-a9b73ef6bfc2

⁽⁷⁾ OJ L 188 I, 15.6.2020, p. 1.

⁽⁸⁾ <http://www.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP9/tabid/7521/Default.aspx>

- (11) After the finalisation of the RAC and SEAC opinion on the proposed restriction for C9-C14 PFCAs, the Commission received two additional requests for exemptions to allow the production of fluoropolymers and fluoroelastomers, as well as the production of polytetrafluoroethylene (PTFE) micro powders and the use in mixtures and articles for industrial and professional applications. The Commission asked ECHA for a supplementary opinion, as the final products are used in high value applications ⁽⁹⁾. The Commission received RAC's and SEAC's supplementary opinion on 15 December 2020 ⁽¹⁰⁾.
- (12) Taking into account the Annex XV dossier, the opinions of RAC and SEAC, the Commission considers that an unacceptable risk to human health and the environment arises from the manufacture, use or placing on the market of linear and/or branched C9-C14 PFCAs, their salts and C9-C14 PFCA- related substances on their own, as a constituent of other substances, in mixtures and in articles, which needs to be addressed on a Union-wide basis. The Commission considers that the proposed restriction, as amended by RAC and SEAC opinions, taking into account its socioeconomic impact and availability of alternatives as well as the alignment of some of the exemptions in this restriction to the exemptions in the amendment of Regulation (EU) 2019/1021 is an appropriate Union-wide measure to address the identified risk.
- (13) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the restriction. Therefore, taking into account the suggestion from the Annex XV dossier as well as RAC's and SEAC's considerations, the application of the restriction should be deferred for 18 months. Longer deferrals or overall exemptions should apply to address the particular cases of specific sectors.
- (14) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 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*.

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

Done at Brussels, 4 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁹⁾ <https://echa.europa.eu/documents/10162/034d97c3-7975-19f5-3739-76c288ad2b0c>

⁽¹⁰⁾ https://echa.europa.eu/documents/10162/13579/art77_3c_pfoa_pfca_derogations_compiled_rac_seac_opinions_en.pdf/6582d9a1-56b2-3e88-a70f-cdf3ab33d421

ANNEX

In Annex XVII, entry 68 is replaced by the following:

'68. Linear and branched perfluorocarboxylic acids of the formula $C_nF_{2n+1}-C(=O)OH$ where $n = 8, 9, 10, 11, 12, \text{ or } 13$ (C9-C14 PFCAs), including their salts, and any combinations thereof;

Any C9-C14 PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}-$ directly attached to another carbon atom, where $n = 8, 9, 10, 11, 12, \text{ or } 13$, including their salts and any combinations thereof;

Any C9-C14 PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}-$ that it is not directly attached to another carbon atom, where $n = 9, 10, 11, 12, 13 \text{ or } 14$ as one of the structural elements, including their salts and any combinations thereof.

The following substances are excluded from this designation

- $C_nF_{2n+1}-X$, where $X = F, Cl, \text{ or } Br$ where $n = 9, 10, 11, 12, 13 \text{ or } 14$, including any combinations thereof,
- $C_nF_{2n+1}-C(=O)OX'$ where $n > 13$ and X' =any group, including salts.

1. Shall not be manufactured, or placed on the market as substances on their own from 25 February 2023.

2. Shall not, from 25 February 2023, be used in, or placed on the market in:

- (a) another substance, as a constituent;
- (b) a mixture;
- (c) an article,

except if the concentration in the substance, the mixture, or the article is below 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA-related substances.

3. By way of derogation to paragraph 2, the concentration limit shall be 10 ppm for the sum of C9-C14 PFCAs, their salts and C9-C14 PFCA related substances, where they are present in a substance to be used as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of this Regulation are met for the manufacturing of fluorochemicals with a perfluoro carbon chain length equal to or shorter than 6 atoms. The Commission shall review this limit no later than 25 August 2023.

4. Paragraph 2 shall apply from 4 July 2023 to:

- (i) textiles for oil- and water-repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety;
- (ii) the manufacture of polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF) for the production of:
 - high performance, corrosion resistant gas filter membranes, water filter membranes and membranes for medical textiles;
 - industrial waste heat exchanger equipment;
 - industrial sealants capable of preventing leakage of volatile organic compounds and PM_{2,5} particulates

5. By way of derogation to paragraph 2, the use of C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall be allowed until 4 July 2025 for:

- (i) photolithography or etch processes in semiconductor manufacturing;
- (ii) photographic coatings applied to films;
- (iii) invasive and implantable medical devices;
- (iv) fire-fighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems, including both mobile and fixed systems, subject to the following conditions:
 - fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall not be used for training;
 - fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall not be used for testing unless all releases are contained;
 - from 1 January 2023, uses of fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall only be allowed to sites where all releases can be contained;
 - fire-fighting foam stockpiles that contain or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall be managed in accordance with Article 5 of Regulation (EU) 2019/1021.

	6. Paragraph 2(c) shall not apply to articles placed on the market before 25 February 2023. 7. Paragraph 2 shall not apply to the can coating for pressurised metered-dose inhalers until 25 August 2028. 8. Paragraph 2 (c) shall apply from 31 December 2023 to: (a) semiconductors on their own; (b) semiconductors incorporated in semi-finished and finished electronic equipment. 9. Paragraph 2(c) shall apply from 31 December 2030 to semiconductors used in spare or replacement parts for finished electronic equipment placed on the market before 31 December 2023. 10. Until 25 August 2024, the concentration limit referred to in paragraph 2 shall be 2 000 ppb for the sum of C9-C14 PFCAs in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups. From 25 August 2024, the concentration limit shall be 100 ppb for the sum of C9-C14 PFCAs, in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups. All emissions of C9-C14 PFCAs during the manufacture and use of fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups shall be avoided and, if not possible, reduced as far as technically and practically possible. This derogation shall not apply to articles referred to in paragraph 2(c). The Commission shall review this derogation no later than 25 August 2024. 11. The concentration limit referred to in paragraph 2 shall be 1 000 ppb for the sum of C9-C14 PFCAs, where these are present in PTFE micro powders produced by ionising irradiation or by thermal degradation, as well as in mixtures and articles for industrial and professional uses containing PTFE micro powders. All emissions of C9-C14 PFCAs during the manufacture and use of PTFE micro powders shall be avoided and, if not possible, reduced as far as technically and practically possible. The Commission shall review this derogation no later than 25 August 2024. 12. For the purposes of this entry, C9-C14 PFCA-related substances are substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to C9-C14 PFCAs.'
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DECISIONS

COUNCIL DECISION (EU) 2021/1298

of 30 July 2021

appointing an alternate member, proposed by the Kingdom of Spain, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to Council Decision (EU) 2019/852 of 21 May 2019 determining the composition of the Committee of the Regions ⁽¹⁾,

Having regard to the proposal of the Spanish Government,

Whereas:

- (1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.
- (2) On 20 January 2020, the Council adopted Decision (EU) 2020/102 ⁽²⁾, appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025.
- (3) An alternate member's seat on the Committee of the Regions has become vacant following the end of the national mandate on the basis of which Mr Juan José MARTÍNEZ LOZANO was proposed for appointment.
- (4) The Spanish Government has proposed Mr Adrián Ariel ZITTELLI FERRARI, representative of a regional body who is politically accountable to an elected assembly, *Director-General de Unión Europea de la Región de Murcia – Asamblea Regional de Murcia* (Director-General for European Union Affairs for the Region of Murcia – Regional Assembly of Murcia), as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025,

HAS ADOPTED THIS DECISION:

Article 1

Mr Adrián Ariel ZITTELLI FERRARI, representative of a regional body who is politically accountable to an elected assembly, *Director-General de Unión Europea de la Región de Murcia – Asamblea Regional de Murcia* (Director-General for European Union Affairs for the Region of Murcia – Regional Assembly of Murcia), is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025.

Article 2

This Decision shall enter into force on the date of its adoption.

⁽¹⁾ OJ L 139, 27.5.2019, p. 13.

⁽²⁾ Council Decision (EU) 2020/102 of 20 January 2020 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 20, 24.1.2020, p. 2).

Done at Brussels, 30 July 2021.

For the Council
The President
G. DOVŽAN

COMMISSION IMPLEMENTING DECISION (EU) 2021/1299**of 4 August 2021****postponing the expiry date of approval of hexaflumuron for use in biocidal products of product-type 18****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance hexaflumuron was approved as an active substance for use in biocidal products of product-type 18 ⁽²⁾.
- (2) The approval of hexaflumuron for use in biocidal products of product-type 18 will expire on 31 March 2022. On 23 September 2020, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of hexaflumuron.
- (3) As hexaflumuron meets the criteria for being a persistent, bioaccumulative and toxic substance (PBT substance), and a very persistent and very bioaccumulative substance (vPvB substance) according to Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁾, it meets the exclusion criteria set out in Article 5(1), point (e), of Regulation (EU) No 528/2012.
- (4) On 18 February 2021, the evaluating competent authority of Greece informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (5) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.
- (6) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.
- (7) Consequently, for reasons beyond the control of the applicant, the approval of hexaflumuron for use in biocidal products of product-type 18 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of hexaflumuron for use in biocidal products of product-type 18 for a period of time sufficient to enable the examination of the application.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2015/1982 of 4 November 2015 approving hexaflumuron as an existing active substance for use in biocidal products for product-type 18 (OJ L 289, 5.11.2015, p. 13).

⁽³⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

- (8) Considering the time-limits for the evaluation by the evaluating competent authority, for the preparation and submission of the opinion by the Agency and the period of time necessary to decide if at least one of the conditions in Article 5(2), first subparagraph, of Regulation (EU) No 528/2012 is fulfilled and whether the approval of hexaflumuron may therefore be renewed, it is appropriate to postpone the expiry date of approval to 30 September 2024.
- (9) Except for the expiry date of approval, hexaflumuron remains approved for use in biocidal products of product-type 18 subject to the specifications and conditions set out in Implementing Regulation (EU) 2015/1982,

HAS ADOPTED THIS DECISION

Article 1

The expiry date of approval of hexaflumuron for use in biocidal products of product-type 18 is postponed to 30 September 2024.

Article 2

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, 4 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

CORRIGENDA

Corrigendum to Commission Delegated Regulation (EU) 2020/1737 of 14 July 2020 amending Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005 as regards the inclusion of certain drug precursors in the list of scheduled substances

(Official Journal of the European Union L 392 of 23 November 2020)

On page 5, in Annex I, in the amendments to Annex I and II to Regulation (EC) 273/2004:

for: '(c) in the entry for Anthranilic acid in the table "SUBCATEGORY 2B", the CN code "2922 43 00" is replaced by "ex 2922 43 00";',

read: '(c) in the entry for Anthranilic acid in the table "SUBCATEGORY 2B", the CN code "2922 43 00" is replaced by "2922 43 00";'.

On page 7, in Annex II, in the amendments to the Annex to Regulation (EC) No 111/2005

for: '(2) the table "Category 2" is amended as follows:
 (a) in the entry for Anthranilic acid, the CN code "2922 43 00" is replaced by "ex 2922 43 00";',

read: '(2) the table "Category 2" is amended as follows:
 (a) in the entry for Anthranilic acid, the CN code "2922 43 00" is replaced by "2922 43 00";'.

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