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(1) Text with EEA relevance.



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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(Non-legislative acts)

## REGULATIONS

## COMMISSION REGULATION (EU) 2020/354

## of 4 March 2020

establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC

(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 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (<sup>1</sup>), and in particular Article 10(5) thereof,

Whereas:

- (1) The placing on the market and use of feed is regulated by Regulation (EC) No 767/2009. In accordance with Article 9 of that Regulation, feed intended for particular nutritional purposes may only be marketed if its intended use is included in a list of intended uses established in accordance with Article 10 of the said Regulation.
- (2) Commission Directive 2008/38/EC (<sup>2</sup>) established a list of intended uses of animal feedingstuffs for particular nutritional purposes.
- (3) Part A of Annex I to Directive 2008/38/EC established the general provisions for feed intended for particular nutritional purposes. Considering scientific and technological developments and the labelling requirements established by Regulation (EC) No 767/2009, those general provisions are to be reviewed.
- (4) Articles 11 to 17 of Regulation (EC) No 767/2009 established new principles and rules for the placing on the market of feed, including labelling. As a consequence, several entries in the list of intended uses of feed intended for particular nutritional purposes contained in Part B of Annex I to Directive 2008/38/EC became outdated, partially because of poor and overly general descriptions in the column 'Essential nutritional characteristics'. For such entries, it has been very difficult for the control authorities to verify compliance with the provisions of Regulation (EC) No 767/2009, including whether the specific composition of the feed concerned fulfils the respective particular intended nutritional purpose.
- (5) In accordance with Article 10 of Regulation (EC) No 767/2009, the Commission received a number of applications to amend and change the conditions associated with several intended uses of feed for particular nutritional purposes, which had become outdated. Outdated entries for which no application has been submitted or for which the application was withdrawn should be removed.

<sup>(&</sup>lt;sup>1</sup>) OJ L 229, 1.9.2009, p. 1.

<sup>(&</sup>lt;sup>2</sup>) Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes (OJ L 62, 6.3.2008, p. 9).

- (6) As regards other intended uses of feed intended for particular nutritional purposes listed in Part B of Annex I to Directive 2008/38/EC, amendments are necessary to the provisions concerning the essential nutritional characteristics and the labelling declarations in order to adapt them to the scientific and technological developments and to improve the enforceability and clarity of the provisions.
- (7) Furthermore, the Commission received, in accordance with Article 10 of Regulation (EC) No 767/2009, applications to add the particular nutritional purposes 'support of energy metabolism and of the muscle function in the case of rhabdomyolosis' and 'support in stressful situations, which will lead to the reduction of associated behaviour' to the list of intended uses of feed intended for particular nutritional purposes.
- (8) The Commission made all applications, including the dossiers, available to the Member States.
- (9) Following the assessment of the dossiers included in those applications, the Standing Committee on Plants, Animals, Food and Feed ('the Committee') acknowledged that the specific composition of the feed concerned fulfils the respective particular intended nutritional purpose and that it has no adverse effects on animal health, human health, the environment or animal welfare.
- (10) Based on the above considerations, the list of intended uses of feed for particular nutritional purposes should be updated.
- (11) Since safety reasons do not require the immediate application of the new general provisions and of the updated list of intended uses of feed for particular nutritional purposes, it is appropriate to provide for transitional measures in order to avoid unnecessary disruption of commercial practices and to not create unnecessary administrative burden on the operators.
- (12) In the interests of clarity and rationality, Directive 2008/38/EC should be repealed and replaced by a Regulation, which does not contain elements that would require transpositions by the Member States into national law. The last amendments to that Directive had already been successively brought through Regulations due to the absence of need of transposition into national law of the provisions concerned. In addition, the general requirements for the placing on the market and use of feed intended for particular nutritional purposes are provided for in Regulation (EC) No 767/2009.
- (13) In order to enable Member States to make the necessary adjustments, an adequate period should be allowed before this Regulation becomes applicable.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Committee,

HAS ADOPTED THIS REGULATION:

## Article 1

Feed intended for particular nutritional purposes within the meaning of Regulation (EC) No 767/2009 may be marketed only if:

- the general provisions for feed intended for particular nutritional purposes laid down in Part A of the Annex to this Regulation are complied with, and
- its intended use is included in Part B of the Annex to this Regulation and the provisions of the respective entry are complied with.

## Article 2

By way of derogation from Article 1, feed intended for particular nutritional purposes which complies with the provisions of Directive 2008/38/EC may continue to be placed on the market, provided that an application for an intended use included therein has been submitted to the Commission in accordance with Article 10 of Regulation (EC) No 767/2009 before 25 March 2021 and until the Commission decides on the respective application.

## Article 3

Feed intended for particular nutritional purposes which has been labelled before 25 March 2022 in accordance with the rules applicable before 25 March 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

## Article 4

Directive 2008/38/EC is repealed.

## Article 5

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 25 December 2020.

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

Done at Brussels, 4 March 2020.

For the Commission The President Ursula VON DER LEYEN

#### ANNEX

## PART A

## General provisions for feed for particular nutritional purposes

- 1. Where there is more than one group of essential nutritional characteristics indicated in column 2 of Part B, denoted by 'and/or', for the same particular nutritional purpose, the manufacturer has the option to use either or both groups of essential characteristics, in order to achieve the particular nutritional purpose defined in column 1 of Part B. For each option the corresponding labelling declarations are given in column 4 of Part B.
- 2. Where an essential nutritional characteristic mentioned in column 2 of Part B is quantitatively indicated, the provisions of Article 17(2) of Regulation (EC) No 767/2009 and the permitted tolerances as established in Annex IV to that Regulation shall apply. If that Annex does not establish a tolerance for the respective labelling particular, a technical deviation of +/- 15 % shall be permitted.
- 3. Where a feed additive is mentioned in column 2 or column 4 of Part B, the authorisation provisions for feed additive(s) in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council (<sup>1</sup>) are applicable and their use shall comply with the specified essential nutritional characteristic.
- 4. Where the declaration of a substance, also authorised as a feed additive, is required in column 4 of Part B and is accompanied by the expression 'total', the total content of the substance shall be labelled under the heading 'analytical constituents'.
- 5. The declarations to be given in accordance with column 4 of Part B shall be quantitative without prejudice to Directive 2004/48/EC of the European Parliament and of the Council (<sup>2</sup>).
- 6. The recommended period of use indicated in column 5 of Part B indicates a range within which the nutritional purpose should normally be achieved. Manufacturers can refer to more precise periods of use, within the fixed limits.
- 7. Where a feed intended for particular nutritional purposes is intended to meet more than one particular nutritional purpose, it shall comply with each respective entry in Part B.
- 8. In the case of complementary feed intended for particular nutritional purposes, guidance on the balance of the daily ration must be provided in the instructions for proper use.
- 9. When a feed intended for particular nutritional purposes is with an appropriate mode of use intended for individual oral administration via a bolus, this shall be established in the column 'other provisions' of the respective feed. Such feed shall exclusively contain, including a potential coating, feed materials and feed additives, unless detailed otherwise in the respective entry. It is recommended that feed intended for individual oral administration is administered by a veterinarian or any other competent person.
- 10. When a feed intended for particular nutritional purposes is placed on the market in the form of a bolus, being a feed material or complementary feed intended for individual oral administration with retarding release, i.e. more than 24 hours, of the compounds, the labelling of such feed shall, if applicable, mention for each feed additive for which a maximum content in complete feed is fixed the maximum period of continuous release of the bolus and the daily release rate. The feed business operator which is placing a bolus on the market shall have the proof that the daily available feed additive level in the digestive tract will not exceed, if applicable, the maximum content of the additive established per kg complete feed during the whole feeding period (retarding release effect). Such proof should be based on a peer reviewed methodology or in-house analysis.
- 11. In case of intended uses for which in column 2 a concentration of certain feed additives higher than 100 times the relevant fixed maximum content in complete feed is allowed for complementary feed, the concentration of those feed additives shall not be higher than 500 times the relevant fixed maximum content in complete feed, except in the case of boluses as referred to in point 10. The incorporation of such complementary feed into the animal's diet shall ensure that the uptake of the animal complies with the fixed maximum content in complete feed.

<sup>(&</sup>lt;sup>1</sup>) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29).

<sup>(&</sup>lt;sup>2</sup>) Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45).

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## List of intended uses

Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
10	function in case	High quality proteins and phos- phorus $\leq 5 \text{ g/kg}$ complete feed with a moisture content of 12 % ( <sup>2</sup> ) and crude protein $\leq 220 \text{ g/kg}$ complete feed with a moisture content of 12 % ( <sup>2</sup> )	Dogs	<ul> <li>Protein source(s)</li> <li>Calcium</li> <li>Phosphorus</li> <li>Potassium</li> <li>Sodium</li> <li>Essential fatty acids (if added)</li> </ul>	Initially up to 6 months ( <sup>3</sup> )	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Recommended digestibility of proteins: minimum 85 %.</li> <li>Indicate on the labelling: 'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> <li>Indicate in the instructions for proper use: 'Water should be available at all times.'</li> </ol>
		Reduced phosphorus absorption by means of incorporation of Lantha- num carbonate octahydrate	Adult dogs	<ul> <li>Protein source(s)</li> <li>Calcium</li> <li>Phosphorus</li> <li>Potassium</li> <li>Sodium</li> <li>Essential fatty acids (if added)</li> <li>Lanthanum carbonate octahydrate</li> </ul>	Initially up to 6 months (³)	<ol> <li>Indicate on the labelling: 'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> <li>Indicate in the instructions for proper use: 'Water should be available at all times.'</li> </ol>
		High quality proteins and phos- phorus $\leq 6,5$ g/kg complete feed with a moisture content of 12 % ( <sup>2</sup> ) and crude protein $\leq 320$ g/kg complete feed with a moisture content of 12 % ( <sup>2</sup> )	Cats	<ul> <li>Protein source(s)</li> <li>Calcium</li> <li>Phosphorus</li> <li>Potassium</li> <li>Sodium</li> <li>Essential fatty acids (if added)</li> </ul>	Initially up to 6 months ( <sup>3</sup> )	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Recommended digestibility of proteins: minimum 85 %.</li> <li>Indicate on the labelling: 'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> <li>Indicate in the instructions for proper use: 'Water should be available at all times.'</li> </ol>
		Reduced phosphorus absorption by means of incorporation of Lantha- num carbonate octahydrate	Adult cats	<ul> <li>Protein source(s)</li> <li>Calcium</li> <li>Phosphorus</li> <li>Potassium</li> <li>Sodium</li> </ul>	Initially up to 6 months (³)	<ol> <li>Indicate on the labelling: 'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> <li>Indicate in the instructions for proper use: 'Water should be available at all times.'</li> </ol>

Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
				<ul> <li>— Essential fatty acids (if added)</li> <li>— Lanthanum carbonate octahydrate</li> </ul>		
		High density of energy with more than 8,8 MJ/kg feed with a moisture content of 12 %. Highly digestible and highly palatable sources of starch. Restricted protein level: $\leq 106$ g crude protein/kg feed with a moisture con- tent of 12 %. Level of sodium: 2 g/100 kg BW per day. High level of eicosapentaenoic acid and docosahexaenoic sum $\geq 0,2$ g per kg BW <sup>0,75</sup> per day	Equines	<ul> <li>Protein and energy source(s)</li> <li>Calcium</li> <li>Phosphorus</li> <li>Potassium</li> <li>Magnesium</li> <li>Sodium</li> <li>Sum of eicosapentae- noic acid and docosa- hexaenoic acid</li> </ul>	Initially up to six months. Long term or until resolu- tion of the issue	<ol> <li>The feed shall be placed on the market as complementary feed</li> <li>Indicate on the labelling:         <ul> <li>'It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.'</li> <li>The complementary feed should not be used in case of hypernatraemia and hyperchloraemia.</li> <li>The complementary feed should contribute to at least 10 to 20 % of the daily energy supply (approximately 0,05 to 0,1 MJ/kg BW<sup>0,75</sup> per day).</li> </ul> </li> <li>The ration should ensure an energy supply of &gt; 0,62 MJ/kg BW<sup>0,75</sup> per day.</li> <li>The ration should not exceed 50 mg calcium/kg dry matter/day.</li> <li>Indicate in the instructions for proper use: 'Water should be available at all times.'</li> </ol>
11	Reduction of oxalate stones formation	Low level of calcium, low level of vi- tamin D, and urine alkalising prop- erties	Dogs and cats	<ul> <li>Phosphorus</li> <li>Calcium</li> <li>Sodium</li> <li>Magnesium</li> <li>Potassium</li> <li>Chlorides</li> <li>Sulphur</li> <li>Vitamin D (total)</li> <li>Hydroxyproline</li> <li>Urine alkalising substances</li> </ul>	Up to 6 months	Indicate on the labelling: 'It is recommended that a veterinarian's opinion be sought before use.'

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
number	1	2	3	4	5	6
12	Regulation of glucose supply (Diabetes melli- tus)	Total sugars (mono- and disacchar- ides) ≤ 62 g/kg complete feed with a moisture of 12 % (²)	Dogs and cats	<ul> <li>Carbohydrate source (s)</li> <li>Treatment of carbohy- drates, if appropriate</li> <li>Starch</li> <li>Total sugars</li> <li>Fructose (if added)</li> <li>Essential fatty acids (if added)</li> <li>Source(s) of short and medium chain fatty acids (if added)</li> </ul>	Initially up to 6 months	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Indicate on the labelling:         <ul> <li>'Low level of mono- and disaccharides'</li> <li>'It is recommended that a veterinarian's opi- nion be sought before use and before extending the period of use.'</li> </ul> </li> </ol>
13	Reduction of in- gredient and nu- trient intoler- ances ( <sup>4</sup> )	Selected and limited number of pro- tein source(s) And/or hydrolysed protein source(s) And/or selected carbohydrate source(s)	Dogs and cats	cluding treatment, if	3 to 8 weeks: if signs of intolerance disappear this feed can be used initially up to one year.	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>It is recommended to limit the number of main protein sources to 3.</li> <li>To indicate on the labelling:         <ul> <li>Appropriate combination of the essential nutritional characteristics, as applicable</li> <li>'It is recommended that a veterinarian's opinion be sought before use and before extending the period of use.'</li> </ul> </li> </ol>
14	Reduction of cy- stine stones for- mation	Urine alkalinising properties and crude protein $\leq 160$ g/kg complete feed with a moisture content of 12 % ( <sup>2</sup> ) Or Proteins selected for a limited cystine and cysteine content (e.g. casein, pea protein, soy protein) and crude pro- tein $\leq 220$ g/kg complete feed with a moisture content of 12 % ( <sup>2</sup> )		<ul> <li>Sulphur amino acids (total)</li> <li>Protein sources</li> <li>Sodium</li> <li>Potassium</li> <li>Chlorides</li> <li>Urine alkalinizing sub- stances (if added)</li> </ul>	Initially up to 6 month	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Indicate in the instructions for proper use: 'Water should be available at all times'</li> <li>Indicate on the labelling:         <ul> <li>'Urine alkalinising properties and low level of proteins' or 'Low level of selected proteins', as applicable.</li> <li>'It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.'</li> </ul> </li> </ol>

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
						<ol> <li>For consideration of the veterinarian or nutrition- ist: Alkalinising properties means that the diet should be formulated to target a urinary pH ≥ 7.</li> </ol>
15	Nutritional re- storation, con- valescence ( <sup>5</sup> )	Highly digestible ingredients with energy density $\ge$ 3 520 kcal and crude protein $\ge$ 250 g per kg of complete feed with a moisture level 12 % ( <sup>2</sup> )		<ul> <li>Highly digestible in- gredient sources in- cluding their treat- ment, if appropriate</li> </ul>	Until restoration is achieved	<ol> <li>Recommended apparent digestibility of Dry Matter ≥ 80 % or of Organic Matter ≥ 85 %.</li> <li>In the case of feed specially presented to be given via tubing, indicate on the package, container or</li> </ol>
		Highly digestible ingredients with energy density $\ge$ 3520 kcal and crude protein $\ge$ 270 g per kg of complete feed with a moisture level 12 % ( <sup>2</sup> )	Cats	— Energy value		<ul> <li>label: 'Administration under veterinary supervision.'</li> <li>The labelling may indicate the specific circumstance(s) the dietetic feed is intended for.</li> <li>Indicate on the labelling: 'High energy density, high concentrations of essential nutrients and highly digestible ingredients'</li> </ul>
16	Reduction of ur- ate stones for- mation	Crude protein ≤ 130 g/kg complete feed with a moisture level of 12 % ( <sup>2</sup> ) Or Crude protein ≤ 220 g/kg complete feed with a moisture level of 12 % ( <sup>2</sup> ) and selected protein sources		— Protein source(s)	Up to 6 months, but life- time use in case of irre- versible disturbance of uric acid metabolism	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Protein quality and level of purines should be taken into account when selecting the protein source. Ex- amples of selected protein sources of high quality with low level of purines include eggs, casein, soy proteins, and maize gluten.</li> <li>Indicate in the instructions for proper use: 'Water should be available at all times'.</li> <li>Indicate on the labelling:         <ul> <li>'It is recommended that a veterinarian's opi- nion be sought before use.'</li> <li>'Low level of protein' or 'Restricted level of pro- tein and selected protein sources', as appropri- ate.</li> </ul> </li> </ol>

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
		Crude protein ≤ 317 g/kg complete feed with a moisture content of 12 % (²)	Cats			<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Protein quality and level of purines should be taken into account when selecting the protein source. Examples of selected protein sources of high quality with low level of purines include eggs, casein, soy proteins, and maize gluten.</li> <li>Indicate on the labelling:         <ul> <li>It is recommended that a veterinarian's opinion be sought before use.'</li> <li>'Restricted level of protein'</li> </ul> </li> <li>Indicate in the instructions for proper use: 'Water should be available at all times'.</li> </ol>
17	Dissolution of struvite stones (°)	Urine undersaturating ( <sup>7</sup> ) properties for struvite And/or Urine acidifying properties ( <sup>8</sup> ) And Magnesium ≤ 1,8 g/kg complete feed with a moisture content of 12 % ( <sup>2</sup> )	Dogs and cats	<ul> <li>Phosphorus</li> <li>Calcium</li> <li>Sodium</li> <li>Magnesium</li> <li>Potassium</li> <li>Chloride</li> <li>Sulfur</li> </ul>	5 to 12 weeks	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Indicate on the labelling:         <ul> <li>'It is recommended that advice from a veteri- narian be sought before use and before extend- ing the period of use.'</li> <li>'Urine undersaturating properties for struvite and/or Urine acidifying properties.'</li> </ul> </li> <li>Indicate in the instructions for proper use: 'Water should be available at all times.'</li> <li>Declaration of conformity supporting undersatur- ating and/or acidifying properties of the diet shall be made available to the relevant competent autho- rities upon request.</li> </ol>
18	Reduction of struvite stone recurrence (°)	Complete feed with urine undersatur- ating ( <sup>7</sup> ) or metastabilising proper- ties ( <sup>9</sup> ) for struvite And/or Diet with urine acidifying proper- ties ( <sup>8</sup> ) And		<ul> <li>Phosphorus</li> <li>Calcium</li> <li>Sodium</li> <li>Magnesium</li> <li>Potassium</li> <li>Chloride</li> <li>Sulfur</li> </ul>	Initially up to 6 month	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Indicate on the labelling:         <ul> <li>Tt is recommended that advice from a veteri- narian be sought before use and before extend- ing the period of use.'</li> <li>'Urine undersaturating or metastabilising properties for struvite and/or Urine acidifying properties'</li> </ul> </li> </ol>

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
		Magnesium $\leq$ 1,8 g/kg complete feed with a moisture content of 12 % ( <sup>2</sup> )				<ol> <li>Indicate in the instructions for proper use: 'Water should be available at all times.'</li> <li>Declaration of conformity supporting undersatur- ating or metastabilising and/or acidifying proper- ties of the diet shall be made available to the rele- vant competent authorities upon request.</li> </ol>
19	Compensation for maldiges- tion ( <sup>10</sup> )	Highly digestible diet: Apparent digestibility of — low-fibre feed (crude fibre $\leq 44$ g per kg of complete feed with a moisture level 12 % ( <sup>2</sup> )): Crude protein $\geq 85$ % Crude fat $\geq 90$ % Or — fibre-enhanced feed (crude fibre $\geq 44$ g per kg of complete feed with a moisture level 12 % ( <sup>2</sup> )): Crude protein $\geq 80$ % Crude fat $\geq 80$ %	Dogs and cats		Initially up to 12 weeks and lifetime in the case of chronic pancreatic insuf- ficiency	
20	Reduction of in- testinal absorp- tive disorders	Highly digestible diet: Apparent digestibility of — low-fibre feed (crude fibre $\leq 44$ g per kg of complete feed with a moisture level 12 % ( <sup>2</sup> )): Crude protein $\geq 85$ % Crude fat $\geq 90$ % Or — fibre-enhanced feed (crude fibre $\geq 44$ g per kg of complete feed with a moisture level 12 % ( <sup>2</sup> )): Crude protein $\geq 80$ % Crude fat $\geq 80$ %	Dogs and cats	<ul> <li>Highly digestible in- gredient sources in- cluding their treat- ment, if appropriate</li> <li>Sodium</li> <li>Potassium</li> </ul>	Up to 12 weeks	<ul> <li>Indicate on the labelling:</li> <li>'Highly digestible feed with increased sodium and potassium'</li> <li>'It is recommended that a veterinarian's opinion be sought before use.'</li> </ul>

Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
		And Sodium $\ge 1.8$ g per kg of complete feed with a moisture level $12 \% (^2)$ And Potassium $\ge 5$ g per kg of complete feed with a moisture level $12 \% (^2)$				
21	Reduction of acute intestinal absorptive dis- orders	Increased level of electrolytes: — Sodium $\geq$ 1,8 % — Potassium $\geq$ 0,6 % And Highly digestible carbohydrates: — $\geq$ 32 %	Dogs and cats	<ul> <li>— Sodium</li> <li>— Potassium</li> <li>— Carbohydrate source (s)</li> </ul>	1 – 7 days	<ol> <li>The feed shall be placed on the market as complementary feed.</li> <li>Indicate on the labelling:         <ul> <li>'During periods of and recovery from acute diarrhoea'</li> <li>'It is recommended that a veterinarian's opinion be sought before use.'</li> </ul> </li> <li>In case of solid feed, the recommended range of electrolytes should be calculated on the basis of a normal daily voluntary intake of water.</li> </ol>
22	Support of lipid metabolism in the case of hy- perlipidaemia	Fat $(^{11}) \le 110 \text{ g/kg}$ complete feed with a moisture content of 12 % $(^{12})$	Dogs and cats	— Crude fat	Initially up to 2 months	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Indicate on the labelling:         <ul> <li>'It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.'</li> <li>'Low level of fat'</li> </ul> </li> </ol>
23	Support of liver function in the case of chronic liver insuffi- ciency	Moderate level of protein: Crude protein $\leq 279$ g/kg complete feed with a moisture content of 12 % ( <sup>2</sup> ) for dogs Crude protein $\leq 370$ g/kg complete feed with a moisture content of 12 % ( <sup>2</sup> ) for cats And Selected protein sources And Recommended dietary protein di- gestibility $\geq 85$ %		<ul> <li>Protein source(s)</li> <li>Copper (total)</li> <li>Sodium</li> </ul>	Initially up to 4 months	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Examples of selected protein sources based on high digestibility: dairy proteins (whey, casein, milk, cot- tage cheese), other animal based proteins (egg, poultry) and vegetable proteins (soy).</li> <li>Indicate in the instructions for proper use: 'Water should be available at all times.'</li> <li>Indicate on the labelling:         <ul> <li>'Moderate level of protein, selected and highly digestible'</li> <li>'It is recommended that a veterinarian's opi- nion be sought before use.'</li> </ul> </li> </ol>

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
		Low level of protein but of high quality and highly digestible carbo- hydrates	Equines	<ul> <li>Protein and fibre sources</li> <li>Highly digestible carbohydrates including their treatment, if appropriate</li> <li>Methionine</li> <li>Choline</li> <li>Content of n-3 fatty acids (if added)</li> </ul>	Initially up to six months	<ol> <li>Indicate on the labelling:         <ul> <li>'It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.'</li> </ul> </li> <li>Guidance should be provided on the manner in which the feed should be fed including many small meals per day.</li> </ol>
24	Support of heart function in the case of chronic cardiac insuffi- ciency	Restricted level of sodium: Sodium $\leq 2,6$ g per kg complete feed with a moisture content of 12 % ( <sup>2</sup> )	Dogs and cats	— Magnesium — Potassium — Sodium	Initially up to 6 months	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Indicate on the labelling: 'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> </ol>
25	Reduction of ex- cessive body weight	complete feed with moisture content of 12 % ( <sup>13</sup> ) Or Metabolizable Energy < 560 kcal/kg complete feed with moisture content of 85 % ( <sup>13</sup> )		— Energy value	Until target body weight is achieved and after if re- quired to maintain target bodyweight	feed.
		Metabolizable Energy < 3190 kcal per kg complete feed with moisture content of 12 % ( <sup>13</sup> ) Or Metabolizable Energy < 580 kcal per kg complete feed with moisture con- tent of 85 % ( <sup>13</sup> )	Cats			<ul> <li>"In laterate on the backhing,"</li> <li>"It is recommended that a veterinarian's opinion be sought before use."</li> <li>"For cats, a transition period when starting the diet is advised."</li> <li>"For an efficient weight loss or ideal weight maintenance, the recommended daily energy intake should not be exceeded."</li> </ul>

Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
26	Support of skin function in the case of dermato- sis and excessive loss of hair	Linoleic acid $\ge$ 12,3 g per kg and sum of eicosapentaenoic acid and doco- sahexaenoic acid $\ge$ 2,9 g per kg of complete feed with a moisture con- tent of 12 % ( <sup>2</sup> )	Dogs and cats	<ul> <li>Linoleic acid</li> <li>Sum of eicosapentae- noic acid and docosa- hexaenoic acid</li> </ul>	Initially up to 2 months	<ul> <li>Indicate on the labelling:</li> <li>'It is recommended that a veterinarian's opinion be sought before use.'</li> <li>'High level of linoleic acid (LA) and of sum of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)'</li> </ul>
		Linoleic acid $\ge$ 18,5 g per kg and sum of eicosapentaenoic acid and doco- sahexaenoic acid $\ge$ 0,39 g per kg of complete feed with a moisture con- tent of 12 % ( <sup>2</sup> )	Dogs			
		Linoleic acid $\ge$ 18,5 g per kg and sum of eicosapentaenoic acid and doco- sahexaenoic acid $\ge$ 0,09 g per kg of complete feed with a moisture con- tent of 12 % ( <sup>2</sup> )	Cats			
27	Support of the metabolism of joints in the case of osteoarthritis	Total omega-3 fatty acids $\ge 29$ g per kg and eicosapentaenoic acid $\ge 3,3$ g per kg complete feed with a moisture content of 12 % ( <sup>2</sup> ) And Adequate levels of vitamin E	Dogs	<ul> <li>Omega-3 fatty acids (total)</li> <li>Eicosapentaenoic acid (total)</li> <li>Vitamin E (total)</li> </ul>	Initially up to 3 months	<ul> <li>Indicate on the labelling:</li> <li>— 'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> </ul>
		Total omega-3 fatty acids $\geq 10,6$ g per kg complete feed with a moisture content of 12 % ( <sup>2</sup> ) and docosahexae- noic acid $\geq 2,5$ g per kg complete feed with a moisture content of 12 % ( <sup>2</sup> ) And Increased levels of methionine and manganese Adequate levels of vitamin E.		<ul> <li>Omega-3 fatty acids (total)</li> <li>Docosahexaenoic acid (total)</li> <li>Methionine (total)</li> <li>Manganese (total)</li> <li>Vitamin E (total)</li> </ul>		

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
28	Reduction of copper in the li- ver	Restricted level of copper: copper ≤ 8,8 mg per kg complete feed with a moisture content of 1 2 % ( <sup>2</sup> )	Dogs	Copper (total)	Initially up to 6 months	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Indicate on the labelling:         <ul> <li>'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> </ul> </li> </ol>
29	Reduction of io- dine levels in feed in case of hy- perthyroidism	Restricted level of iodine: iodine ≤ 0,26 mg per kg complete feed with a moisture content of 12 % (²)	Cats	Iodine (total)	Initially up to 3 months	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Indicate on the labelling:         <ul> <li>'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> </ul> </li> </ol>
30	Support in stressful situa- tions, which will lead to the re- duction of asso- ciated behaviour	1-3 g trypsin-hydrolysed bovine casein per kg complete feed with a moisture content of 12 % ( <sup>2</sup> )	Dogs	Trypsin-hydrolysed bo- vine casein	Initially up to 2 months	<ol> <li>The feed shall be placed on the market as complete feed.</li> <li>Indicate on the labelling:         <ul> <li>'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> </ul> </li> </ol>
50	Support the pre- paration for oes- trus and repro- duction	<ul> <li>High level of selenium and a minimum content of vitamin E per kg complete feed with a moisture content of 12 % for pigs of 50 mg, rabbits of 35 mg, for dogs, cats, mink of 88 mg; a minimum content of vitamin E per animal and day for ovines of 100 mg, cattle of 300 mg, horses of 1 100 mg</li> <li>Or</li> <li>High level(s) of vitamins A and/or vitamin D and/or a minimum content of beta- carotene of 300 mg per animal and day.</li> </ul>		Names and total amounts of each added trace ele- ment and vitamin	<ul> <li>Cows: 2 weeks before the end of gestation until the next gesta- tion is confirmed.</li> <li>Sows: 7 days before until 3 days after par- turition and 7 days be- fore until 3 days mat- ing.</li> <li>Other female mam- mals: from the last part of gestation until the next gestation is confirmed.</li> </ul>	<ol> <li>Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, nonbioavailable form, in order to increase its density.</li> <li>The instructions for proper use for the feed shall ensure that the respective legal maximum contents for complete feed are respected.</li> <li>Indicate on the labelling of the feed guidance on the situations in which the use of the feed is appropriate.</li> </ol>

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
		The complementary feed may con- tain selenium, vitamin A and D in a concentration higher than 100 times the relevant fixed maximum content in complete feed.			<ul> <li>Males: during periods of reproductive activ- ity.</li> </ul>	
		<ul> <li>High level(s) of vitamin A and/or vitamin D</li> <li>Or</li> <li>High level(s) of selenium and/or zinc and/or a minimum content of vitamin E of 40 mg/kg complete feed with a moisture content of 12 %.</li> <li>The complementary feed may contain selenium, zinc, vitamin A and D in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</li> </ul>	Birds	Names and total amounts of each added trace ele- ment and vitamin	<ul> <li>For females: during oestrus</li> <li>For males: during periods of reproductive activity</li> </ul>	
1	Support the re- generation of hooves, trotters and skin	High level of zinc. The complementary feed may con- tain zinc in a concentration higher than 100 times the relevant fixed maximum content in complete feed.	Horses, ru- minants and pigs	<ul> <li>Zinc (total)</li> <li>Methionine (total)</li> <li>Biotin (if added)</li> </ul>	Up to 8 weeks	<ol> <li>The instructions for proper use for the feed shall ensure that the legal maximum contents of zinc for complete feed are respected.</li> <li>Application in the form of bolus is allowed for ru- minants. A bolus may contain up to 20 % iron in an inert, non-bioavailable form, in order to increase its density.</li> </ol>
2	Support for nu- tritional imbal- ances in dietary transition	<ul> <li>Minimum supply via the dietetic feed of:</li> <li>Selenium: 0,1 mg/kg complete feed with a moisture content of 12 %</li> <li>And/or</li> <li>Zinc: 15 mg/kg complete feed with a moisture content of 12 %</li> <li>And/or</li> <li>Copper: 2 mg/kg complete feed with a moisture content of 12 % for sheep and 5 mg/kg complete feed with a moisture content of 12 % for sheep and 5 mg/kg complete feed with a moisture content of 12 %</li> </ul>	Pigs Rabbits	Name and total amount of the nutritional additives, if appropriate	2 to 15 days	<ol> <li>Application in the form of bolus is allowed for ruminants and pigs. A bolus may contain up to 20 % iron in an inert, non-bioavailable form, in order to increase its density.</li> <li>The instructions for proper use for the feed shall ensure that the respective legal maximum contents for complete feed are respected.</li> </ol>

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
		<ul> <li>Vitamin A: 2000 IU/kg complete feed with a moisture content of 12 %</li> <li>And/or</li> <li>Vitamin D: 400 IU/kg complete feed with a moisture content of 12 %</li> <li>And/or</li> <li>Vitamin E: 35 mg/kg complete feed with a moisture content of 12 % for poultry, 10 mg/kg complete feed with a moisture content of 12 % for ruminants, 40 mg/kg complete feed with a moisture content of 12 % for rabbits and 20 mg/kg complete feed feed feed for pigs with a moisture content of 12 % The complementary feed may contain selenium, zinc, copper, vitamin A and vitamin D in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</li> </ul>				3. Indicate on the labelling of the feed guidance on the situations in which the use of the feed is appropriate.
3	Support wean- ing	<ul> <li>Minimum supply via the dietetic feed of:</li> <li>— Selenium: 0,1 mg/kg complete feed with a moisture content of 12 %</li> </ul>	Mammals	Name and total amount of the nutritional additives, if appropriate		<ol> <li>The instructions for proper use for the feed shall ensure that the respective legal maximum contents for complete feed are respected.</li> <li>Indicate on the labelling of the feed guidance on the situations in which the use of the feed is appropri- ate.</li> </ol>

Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions	5.3.2020
	1	2	3	4	5	6	
		<ul> <li>And/or</li> <li>Zinc: 15 mg/kg complete feed with a moisture content of 12 % And/or</li> <li>Copper: 2 mg/kg complete feed with a moisture content of 12 % for sheep and 5 mg/kg complete feed with a moisture content of 12 % for other species</li> <li>And/or</li> <li>Iodine: 0,2 mg/kg complete feed with a moisture content of 12 % And/or</li> <li>Manganese: 20 mg/kg complete feed with a moisture content of 12 % And/or</li> <li>Manganese: 20 mg/kg complete feed with a moisture content of 12 % And/or</li> <li>Vitamin A: 1500 IU/kg complete feed with a moisture content of 12 % And/or</li> <li>Vitamin D: 400 IU/kg complete feed with a moisture content of 12 % And/or</li> <li>Vitamin D: 400 IU/kg complete feed with a moisture content of 12 % And/or</li> <li>Titamin E: 100 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg/kg complete feed with a moisture content of 12 % for calves and 50 mg</li></ul>		Υ			EN Official Journal of the European Union

Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
54	Support the re- generation of the skin and appen- dages	<ul> <li>Minimum supply of zinc compounds via dietetic feed corresponding to 20 mg/kg complete feed with a moisture content of 12%</li> <li>And</li> <li>High level of copper and/or iodine and/or selenium and/or vitamin B6 and/or vitamin E and/or vitamin A and/or methionine and/or cystine and/or methionine and/or cystine and/or minimum supply of 0,4 mg biotin/kg complete feed with a moisture content of 12% for ruminants. The complementary feed may contain zinc, copper, iodine, selenium and vitamin A in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</li> </ul>	and poultry	Name and total amount of the nutritional additives, if appropriate	<ul> <li>Up to 8 weeks</li> <li>Complementary feed for ruminants con- taining biotin: Up to 6 months</li> </ul>	
55	Stabilisation of water and elec- trolyte balance to support the physiological di- gestion	<ul> <li>Predominantly electrolytes: so- dium, potassium and chlorides</li> <li>Buffering capacity (<sup>19</sup>) in case of liquid feed: minimum 60 mmol per litre potion ready prepared for feeding</li> <li>Easily digestible carbohydrates</li> </ul>	lambs, kids	<ul> <li>Sodium</li> <li>Potassium</li> <li>Chlorides</li> <li>Carbohydrate source (s)</li> <li>Bicarbonates and/or citrates (if added)</li> </ul>	1 to 7 days	<ol> <li>Recommended range of electrolytes per litre potion ready prepared for feeding: Sodium: 1.7 g - 3.5 g Potassium: 0.4 g - 2 g Chlorides: 1 g - 2.8 g</li> <li>In case of solid feed, the recommended range of electrolytes should be calculated on the basis of a normal daily voluntary intake of water.</li> </ol>

Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
						<ul> <li>3. Indicate on the labelling: <ul> <li>'In case of risk of, during periods of, or recovery from digestive disturbance (diarrhoea).'</li> <li>'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> </ul> </li> <li>4. Indicate in the instructions for proper use: <ul> <li>The recommended intake of the ready stirred potion and of milk, if appropriate.</li> <li>In case of bicarbonates and/or citrates are above 40 mmol per litre potion ready prepared for feeding of ruminants: 'Simultaneous feeding of milk should be avoided in animals with abomasum'</li> </ul> </li> </ul>
56	Reduction of the risk of tetany (hypomagnesae- mia)	High level of magnesium, easily available carbohydrates, moderate level of protein and low level of potassium	Ruminants	<ul> <li>Starch</li> <li>Sugars (total)</li> <li>Magnesium</li> <li>Sodium</li> <li>Potassium</li> </ul>	3 to 10 weeks during periods of fast grass growth	<ol> <li>Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, nonbioavailable form, in order to increase its density.</li> <li>In the instructions for proper use guidance shall be provided on the balance of the daily ration, with regard to the inclusion of fibre and easily available energy sources.</li> <li>In the case of feed for ovines indicate on the labelling: 'Especially for lactating ewes.'</li> </ol>
57	Reduction of the risk of acidosis	Low level of easily fermentable car- bohydrates and high buffering capa- city	Ruminants	— Starch — Sugars (total)	up to 2 months ( <sup>15</sup> )	<ol> <li>Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, nonbioavailable form, in order to increase its density.</li> <li>In the instructions for proper use guidance shall be provided on the balance of the daily ration, with regard to the inclusion of fibre and easily fermentable carbohydrate sources.</li> <li>In the case of feed for dairy cows indicate on the labelling: 'Especially for high yielding cows.'</li> <li>In the case of feed for ruminants for fattening indicate on the labelling: 'Especially for intensively fed (<sup>16</sup>).'</li> </ol>

Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
58	Reduction of the risk of urinary calculi	Low level of phosphorus, magne- sium, and urine acidifying properties	Ruminants	<ul> <li>Calcium</li> <li>Phosphorus</li> <li>Sodium</li> <li>Magnesium</li> <li>Potassium</li> <li>Chlorides</li> <li>Sulphur</li> <li>Urine acidifying substances</li> </ul>	Up to 6 weeks	<ol> <li>Indicate on the labelling: 'Especially for intensively fed young animals.'</li> <li>Indicate in the instructions for proper use: 'Water should be available at all times.'</li> </ol>
59	Long-term sup- ply of grazing animals with trace elements and/or vitamins	<ul> <li>High level of <ul> <li>Trace elements</li> </ul> </li> <li>And/or <ul> <li>Vitamins, provitamins and chemically well-defined substances having similar effects.</li> </ul> </li> <li>The complementary feed may contain feed additives in a concentration higher than 100 times the relevant fixed maximum content in complete feed</li> </ul>	Ruminants with a functional rumen	<ul> <li>Names and total amounts of each added trace element, vitamin, provitamin and chemically well-defined substance having similar effects</li> <li>Daily release rate for each trace element and/or vitamin if a bolus is used</li> <li>Maximum period of continuously release of the trace element or vitamin if a bolus is used</li> </ul>	Up to 12 months	<ol> <li>Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, nonbioavailable form, in order to increase its density.</li> <li>Indicate on the labelling of the feed:         <ul> <li>"Simultaneous supplementation of additives with a maximum content from other sources to those incorporated in a bolus, if applicable, shall be avoided.</li> <li>Before using, it is recommended to have advice from a veterinarian or nutritionist concerning:</li></ul></li></ol>
60		Low cations/anions ratio For the total ration: — Minimum acidification via feed for particular nutritional pur- pose: 100 mEq/kg dry matter — Objective: 0 < DCAD ( <sup>17</sup> ) (mEq/kg dry matter) < 100	Dairy cows	<ul> <li>Calcium</li> <li>Phosphorus</li> <li>Magnesium</li> <li>Sodium</li> <li>Potassium</li> <li>Chlorides</li> <li>Sulphur</li> </ul>	From 3 weeks before cal- ving until calving	Indicate in the instructions for proper use: 'Stop feeding after calving'

Entry umber	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
		Or				
		Zeolite (sodium aluminium silicate): 250 – 500 g/day		Sodium aluminium sili- cate	From 3 weeks before cal- ving until calving	<ul> <li>Indicate in the instructions for proper use:</li> <li>- 'The amount of feed shall be restricted to ensure that a daily intake of 500 g sodium aluminium-silicate per animal is not exceeded.'</li> <li>- The duration of use shall be restricted to a maximum of 2 weeks.</li> <li>- 'Stop feeding after calving'</li> </ul>
		Or Supply of rumen protected feed ma- terials rich in phytic acid (> 6 %) and having a calcium content < 0,2 %, to achieve a minimum of 28 g and a maximum of 32 g available calcium per cow per day. Or		— Calcium	From 4 weeks before cal- ving until calving	Indicate in the instructions for proper use: 'Stop feeding after calving'
		High level of calcium in the form of highly available sources of calcium: calcium chloride and/or calcium sul- fate and/or dicalcium phosphate an- d/or calcium carbonate and/or cal- cium propionate and/or calcium formate. and/or 'any other calcium source having a similar effect' Calcium provided by one or a combi- nation of these sources with a mini- mum of 50 g per cow per day Or		— Calcium — Calcium sources	From first signs of par- turition to two days Subsequent to parturition	<ol> <li>Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, nonbioavailable form, in order to increase its density.</li> <li>Indicate in the instructions for proper use the number of applications and the time before and after calving.</li> <li>Indicate on the labelling: 'It is recommended that a nutritional expert's opinion be sought before use'.</li> </ol>
		Calcium pidolate in a minimum of 5,5 g per cow per day Or		— Calcium — Calcium pidolate	From first signs of par- turition to two days sub- sequent to parturition	<ol> <li>Application in the form of bolus is allowed. A bo- lus may contain up to 20 % iron in an inert, non- bioavailable form, in order to increase its density.</li> </ol>

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
_	1	2	3	4	5	6
						2. Indicate on the labelling: 'It is recommended that a nutritional expert's opinion be sought before use'.
		Waxy-leaf nightshade meal allowing a daily release of 38 – 46 µg 1,25 dihydroxycholecalciferol-glycoside per day		meal	From two days before calving or first signs of parturition to 10 days subsequent to parturition	<ol> <li>Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, nonbioavailable form, in order to increase its density.</li> <li>Indicate on the labelling: 'It is recommended that a nutritional expert's opinion be sought before use'.</li> </ol>
61	Reduction of the risk of ketosis ( <sup>18</sup> )	<ul> <li>Minimum supply of propane- 1,2-diol or propylene glycol: 250 g/day for dairy cows 50 g/day for dairy cows</li> <li>Or</li> <li>Minimum supply of propionates (calcium or sodium salts): 110 g/day for dairy cows 22 g/day for ewes or goats</li> <li>Or</li> <li>Minimum combined supply of propane-1,2-diol and propio- nates (sodium or calcium salts), as long as:</li> <li>The combination of propane- 1,2-diol and propionates for dairy cows is such that propio- nates + 0,44 x propane-1,2 diol &gt; 110 g/day</li> </ul>	Dairy cows, ewes and goats	added — Propionates in the	Between three weeks be- fore and six weeks after calving for dairy cows Between six weeks before and three weeks after par- turition for ewes and goats	<ul><li>lus may contain up to 20 % iron in an inert, non-bioavailable form, in order to increase its density.</li><li>Indicate on the labelling: 'During the supply of calcium or sodium propionates at the end of gesta-</li></ul>

Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
		<ul> <li>The combination of propane- 1,2-diol and propionates for ewes or goats is such that propio- nates + 0,44 x propane-1,2 diol &gt; 22 g/day</li> </ul>				
62	Reduction of stress reactions	<ul> <li>High level magnesium</li> <li>And/or</li> <li>Highly digestible ingredients</li> </ul>	Pigs	<ul> <li>Magnesium</li> <li>Highly digestible in- gredients including their treatment if ap- propriate</li> <li>Content of n-3 fatty acids (if added)</li> </ul>	1 to 7 days	Guidance shall be provided on the situation in which the use of this feed is appropriate.
63	Reduction of the risk of constipa-tion	Ingredients stimulating intestinal passage	Sows	Ingredients stimulating intestinal passage	10 to 14 days before and 10 to 14 days after farrowing	
64	Compensation for insufficient iron availability after birth	High level of iron compounds authorised under the functional group 'compounds of trace elements' of the category 'nutritional additives' as referred to in Annex I to Regulation (EC) No 1831/2003. The complementary feed may con- tain iron in a concentration higher than 100 times the relevant fixed maximum content in complete feed.	piglets and calves	Iron (total)	After birth up to 3 weeks	The instructions for proper use shall ensure that the legal maximum contents of iron for complete feed are respected.

Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
65	Compensation for malabsorp- tion	Low level of saturated fatty acids and high level of fat soluble vitamins	Poultry ex- cluding geese and pigeons	<ul> <li>Percentage of saturated fatty acids in relation to total fatty acids</li> <li>Vitamin A (total)</li> <li>Vitamin D (total)</li> <li>Vitamin E (total)</li> <li>Vitamin K (total)</li> </ul>	During the first 2 weeks after hatching	
66	Reduction of the risk of fatty liver syndrome	Low energy and high proportion of metabolisable energy from lipids with high level of polyunsaturated fatty acids	Laying hens	<ul> <li>Energy value (calculated according to EC method)</li> <li>Percentage of metabolisable energy from lipids</li> <li>Content of poly-unsaturated fatty acids</li> </ul>	Up to 12 weeks	
67	Support the pre- paration for and recovery from sport effort	High level of selenium and a mini- mum content of 50 mg vitamin E per kg complete feed with moisture content of 12 %. The complementary feed may con- tain compounds of selenium in a con- centration higher than 100 times the relevant fixed maximum content in complete feed.		— Vitamin E (total) — Selenium (total)	Up to 8 weeks before sport effort – Up to 4 weeks after sport effort	The instructions for proper use for the feed shall en- sure that the legal maximum contents of selenium for complete feed are respected.
68	Compensation of electrolyte loss in the cases of heavy sweat- ing	Must contain sodium chloride and should contain potassium chloride. Low levels of Magnesium, Calcium and Phosphorus The inclusion of other electrolyte salts is optional.		<ul> <li>— Sodium</li> <li>— Chlorides</li> <li>— Potassium</li> <li>— Calcium</li> <li>— Magnesium</li> <li>— Phosphorus</li> </ul>	One to three days after heavy sweating.	<ol> <li>Guidance shall be provided on the situations in which the use of the feed is appropriate.</li> <li>The instructions for proper use must give admin- istration guidelines based on the duration and in- tensity of exercise performed relevant to the for- mulation and presentation of the feed.</li> </ol>

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
						<ol> <li>Indicate on the labelling:         <ul> <li>'Water should be available at all times.'</li> <li>In the case of the administration of electrolytes not mixed with water (e.g. in feed or in syringe format): 'Water must be available for at least 20 minutes or preferably for 1 hour post administration.'</li> </ul> </li> <li>Furthermore guidance must be given to monitor subsequent drinking, if insufficient water intake is observed veterinary advice should be sought.</li> <li>Guidance may optionally be given regarding the quantity of water (in litres) to be provided alongside in feed or syringed electrolytes.</li> </ol>
69	Support of en- ergy metabolism and of the mus- cle function in the case of rhab- domyolosis	Starch and sugar not more than 20 % of available energy. Crude fat more than 20 % of available energy Minimum of 350 IU Vitamin E/kg complete feed with a moisture con- tent of 12 %	Equines	<ul> <li>Starch</li> <li>Sugar</li> <li>Crude fat</li> <li>Vitamin E (total)</li> </ul>	Initially for a minimum of 3 months	<ol> <li>Guidance shall be provided on the situations in which the use of this feed is appropriate.</li> <li>The instructions for proper use shall contain gui- dance on the balance of the daily ration and the appropriate daily intake.</li> <li>Indicate on the labelling: 'It is recommended that a veterinarian's opinion be sought before use.'</li> </ol>
70	Compensation for chronic di- gestive disorders of large intestine	<ul> <li>Starch content to provide &lt; 1 g/kg BW/meal (&lt; 0,5 g/kg BW/meal, if diarrhoea present)</li> <li>Cereal grains processed via a hy- drothermal treatment, such as ex- trusion, micronisation, expan- sion or flaking, to improve small intestinal starch digestion</li> </ul>		— Starch — Crude fat	Long term or until reso- lution of the issue	<ol> <li>Guidance shall be provided         <ul> <li>on the precise situations in which the use of the feed is appropriate, in particular whether the product is for use in animals with concurrent diarrhoea or not.</li> <li>on meal size and forage intake.</li> </ul> </li> <li>The instructions for proper use shall refer, depending on the oil content, to the potential gradual use and suggest a monitoring for diarrhoea.</li> </ol>

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Entry number	Particular nutritional purpose	Essential nutritional characteristics (GP1)	Species or category of animal	Labelling declarations (GP2)	Recommended length of time	Other provisions
	1	2	3	4	5	6
		<ul> <li>Additional supply of water soluble vitamins and adequate minerals/electrolytes levels</li> <li>Additional supply of oil if no diarrhoea</li> </ul>				<ol> <li>Indicate on the labelling the processing used for the cereal grains.</li> </ol>
71	Compensation for chronic in- sufficiency of small intestine function	<ul> <li>Highly digestible fibres</li> <li>High quality protein sources and lysine &gt; 4,3 % of crude protein</li> <li>Total sugar and starch to provide a maximum of 0,5 g/kg BW/meal</li> <li>Cereal grains processed via a hy- drothermal treatment, such as ex- trusion, micronisation, expan- sion or flaking, to improve pre- caecal digestion</li> </ul>		<ul> <li>Highly digestible feed materials including their processing, if ap- propriate.</li> <li>Total sugar and starch</li> <li>Protein sources</li> </ul>		<ol> <li>Guidance shall be provided on         <ul> <li>the precise situations in which the use of the feed is appropriate</li> <li>meal size and forage intake.</li> </ul> </li> <li>The instructions for proper use shall refer, depending on the oil content, to the potential gradual use and suggest a monitoring for diarrhoea.</li> </ol>
72	Stabilisation of the physiological digestion	Feed additives of the functional group 'Gut flora stabiliser' as referred to in Annex I to Regulation (EC) No 1831/2003 or, pending the re- authorisation procedure as referred to in Article 10 of Regulation (EC) No 1831/2003, feed additives of the group 'micro-organisms'	cies for which the gut flora stabiliser or micro-or-	Name and added amount of the gut flora stabiliser or micro- organism	Up to 4 weeks	<ol> <li>Indicate on the labelling: <sup>1</sup>In case of risk of, during periods of, or recovery from digestive disturbance'.         <ol> <li>The instructions for proper use of the feed shall ensure that the legal maximum content of the gut flora stabiliser or micro-organism for complete feed is respected.         </li> </ol> </li></ol>

(GP1) For the control of the quantitative indications, the tolerances as established in Annex IV of Regulation (EC) No 767/2009 apply.

(GP2) These labelling declarations apply in addition to the general labelling requirements laid down in Regulation (EC) No 767/2009

(1) If appropriate the manufacturer may also recommend use for temporary renal insufficiency.

(2) based on a diet with a dry matter energy density of 4000 kcal Metabolisable Energy/kg calculated using the equation described in the FEDIAF Nutritional Guidelines (http://www.fediaf.org/self-regulation/nutrition.html). The values shall be adapted if the energy density deviates from the 4000 kcal Metabolisable Energy/kg.

(3) If the feed is recommended for temporary renal insufficiency the recommended period for use shall be two to four weeks.

(4) In the case of feed for a particular intolerance, reference to the specific intolerance can replace 'ingredient and nutrient'

(<sup>5</sup>) For cats a reference to 'Feline hepatic lipidosis' may be added

(6) For cats, 'feline lower urinary tract disease' or 'feline urological syndrome – FUS' may be added.

() Undersaturating properties: urine associated with crystal and stone dissolution properties and/or properties of prevention of crystal precipitation and growth.

(8) Urine pH  $\leq 6,5$ .

(\*) Metastabilising properties: urine associated with properties of prevention of crystal precipitation.

(<sup>10</sup>) 'exocrine pancreatic insufficiency' may be added.

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(<sup>11</sup>) The minimum recommendations according to the FEDIAF Nutritional Guidelines (http://www.fediaf.org/self-regulation/nutrition.html) for all essential fatty acids shall be met in the daily ration. (<sup>12</sup>) based on a diet with a dry matter energy density of 3500 kcal Metabolisable Energy/kg calculated using the equation described in the FEDIAF Nutritional Guidelines

(http://www.fediaf.org/self-regulation/nutrition.html). The values shall be adapted if the energy density deviates from the 3500 kcal Metabolisable Energy/kg.

(13) Metabolisable Energy/kg calculated using the equation described in the FEDIAF (2019) Nutritional Guidelines for Complete and Complementary Pet Food for Cats and Dogs.

(14) FEDIAF (2019) Nutritional Guidelines for Complete and Complementary Pet Food for Cats and Dogs.

(15) In the case of feed for dairy cows: 'maximum two months from the start of lactation'.

(<sup>16</sup>) Indicate the category of ruminants concerned.

(<sup>17</sup>) DCAD (mEq/kg dry matter) = (Na + K) - (Cl + S).

(<sup>18</sup>) The term 'ketosis' may be replaced by 'acetonaemia' and the person responsible for the labelling may also recommend the use for ketosis recuperation.

(19) Calculated by the Strong Ion Difference method (SID-Value): SID is the difference between the sums of concentrations of the strong cations and strong anions; [SID] = [mmol Na<sup>+</sup>/l] + [mmol Ca<sup>+</sup> + [mmol Ca<sup>+</sup>] + [mmol Ca<sup>+</sup>]

 $^{+}/l] + [mmol Mg^{++}/l] - [mmol Cl^{-}/l] - [mmol Other Strong Anions/l].$ 

## COMMISSION REGULATION (EU) 2020/355

## of 26 February 2020

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyglycerol polyricinoleate (E 476) in liquid vegetable oil emulsions

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (<sup>1</sup>), and in particular Article 10(3) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council (<sup>2</sup>), either on the initiative of the Commission or following an application.
- (3) Pursuant to Annex II to Regulation (EC) No 1333/2008 polyglycerol polyricinoleate (E 476) is an already authorised food additive in food category 02.2.2 'Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1234/2007 and liquid emulsions' (at a maximum level of 4 000 mg/kg), but only for spreadable fats as defined in Article 115 of Council Regulation (EC) No 1234/2007 (<sup>3</sup>) and Annex XV thereto, having a fat content of 41 % or less and similar spreadable products with a fat content of less than 10 % fat. Regulation (EC) No 1234/2007 has been later repealed by Regulation (EU) No 1308/2013 of the European Parliament and of the Council (<sup>4</sup>).
- (4) On 27 May 2017, an application was submitted for the authorisation of the use of polyglycerol polyricinoleate (E 476) as an emulsifier in liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70 % or less. The application was subsequently made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) Polyglycerol polyricinoleate (E 476) is a water-in-oil emulsifier capable of forming very stable oil emulsions with high water content. In studies carried out by the applicant, comparing the effectiveness of different emulsifiers for the production of liquid vegetable oil emulsions with reduced fat content, polyglycerol polyricinoleate (E 476) gave the best results both in terms of physical as well as organoleptic properties of the obtained product. The emulsion can be used in the same way as vegetable oils for the preparation of cold and hot dishes. However, the emulsion has a lower fat content (70 % or less), and therefore a lower caloric content than the vegetable oil used for its production. The level of use of polyglycerol polyricinoleate (E 476) needed to achieve the intended technological function was 4 000 mg/kg.
- (6) On 24 March 2017, the European Food Safety Authority ('the Authority') delivered a scientific opinion on the reevaluation of polyglycerol polyricinoleate (E 476) (<sup>3</sup>) and established an acceptable daily intake (ADI) of 25 mg polyglycerol polyricinoleate/kg body weight/day. Considering that the exposure estimates did not exceed the ADI, the Authority concluded that polyglycerol polyricinoleate (E 476) as a food additive would not be of safety concern, if used at the permitted or reported use and use levels

<sup>(1)</sup> OJ L 354, 31.12.2008, p. 16.

<sup>(2)</sup> Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).

<sup>&</sup>lt;sup>(3)</sup> Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) (OJ L 299, 16.11.2007, p. 1).

<sup>(\*)</sup> 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 (OJ L 347, 20.12.2013, p. 671).

<sup>(&</sup>lt;sup>5</sup>) EFSA Journal 2017;15(3):4743.

- (7) In the application the applicant estimated the exposure by using the Food Additives Intake Model (<sup>6</sup>) developed by the Authority. The estimates provided indicate that the additional use of polyglycerol polyricinoleate (E 476) at the maximum level of 4 000 mg/kg in liquid vegetable oil emulsions having a fat content of 70 % or less, is not of safety concern, since it would not result in a total exposure to this substance exceeding the established ADI.
- (8) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the Authority in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health.
- (9) Since the extended use of polyglycerol polyricinoleate (E 476) in food category 02.2.2 is not of safety concern, it requires an update of the Union list, which is not liable to have an effect on human health and hence it is not necessary to seek the opinion of the Authority.
- (10) Therefore, it is appropriate to authorise the use of polyglycerol polyricinolate (E 476) as an emulsifier in liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70 % or less, in food category 02.2.2 'Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1234/2007 and liquid emulsions'.
- (11) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 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, 26 February 2020.

For the Commission The President Ursula VON DER LEYEN

<sup>(\*)</sup> https://www.efsa.europa.eu/en/applications/foodingredients/tools

## 5.3.2020

## ANNEX

In Part E of Annex II to Regulation (EC) No 1333/2008, in food category 02.2.2 'Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1234/2007 and liquid emulsions', the entry for polyglycerol polyricinoleate (E 476) is replaced by the following:

ʻE 476	Polyglycerol polyricinoleate	4000	only spreadable fats as defined in Articles 75(1)(h) and 78(1)(f) and in Part VII and Appendix II of Annex VII to Regulation (EC) No 1308/2013 (*), having a fat content of 41 % or less and similar spreadable products with a fat content of less than 10 % fat; liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70 % or less
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(\*) OJ L 347, 20.12.2013, p. 67.'

## **COMMISSION REGULATION (EU) 2020/356**

## of 4 March 2020

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polysorbates (E 432-436) in carbonated beverages

(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (<sup>1</sup>), and in particular Article 10(3) thereof,

Whereas:

- Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food and their conditions of use.
- (2) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council (<sup>2</sup>), either on the initiative of the Commission or following an application.
- (3) Pursuant to Annex II to Regulation (EC) No 1333/2008, polyoxyethylene sorbitan tristearate (polysorbate 65) (E 436) is currently authorised for use as a food additive in the group 'polysorbates' (E 432-436) in a wide variety of foods at maximum levels ranging between 500 and 10 000 mg/kg and *quantum satis* in food supplements.
- (4) On 4 July 2018, an application was submitted for the authorisation of the use of polysorbate 65 (E 436) as an antifoaming agent in several types of beverages. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) It results from the application that, the proposed use of polysorbate 65 (E 436) is required at the maximum level of 10 mg/kg for containment and inhibition of foam during the manufacture of carbonated beverages by forming a layer around bubbles and stabilising larger bubbles preventing them to coalesce and break. The application shows that, the inhibition of foam is needed to efficiently operate the production equipment, to reduce product waste, to maintain a safe workplace, and to keep facilities clean and in a hygienic state.
- (6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has to seek the opinion of the European Food Safety Authority ('the Authority') in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health.
- (7) The safety of polysorbates (E 432-436) used as food additives was re-evaluated by the Authority in 2015 (<sup>3</sup>). The Authority concluded that the exposure estimates did not exceed the acceptable daily intake (ADI) of 25 mg/kg body weight/day in the refined non-brand-loyal scenario for all age groups at both the mean exposure level and the high level; although for toddlers at the highest level they were very close to the ADI. The Authority noted that more data were needed to decrease uncertainties in the refined exposure assessment scenario used since no reported uses had been obtained for three food categories and that other dietary sources of exposure to polysorbates could not be considered in the opinion.

<sup>&</sup>lt;sup>(1)</sup> OJ L 354, 31.12.2008, p. 16.

<sup>(&</sup>lt;sup>2</sup>) Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).

<sup>(&</sup>lt;sup>3</sup>) EFSA Journal 2015;13(7):4152.

- (8) In the application the applicant estimated the exposure by using the Food Additives Intake Model (\*) developed by the Authority. The estimates provided indicate that the additional exposure due to the requested extension of use is negligible (below 1 % of the ADI).
- (9) The extended use of polysorbate 65 (E 436) at the maximum level of 10 mg/kg in the food categories 14.1.4 'Flavoured drinks', 14.2.3 'Cider and perry', 14.2.4 'Fruit wine and made wine' and 14.2.8 'Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol' in Part E of Annex II to Regulation (EC) No 1333/2008 requires an update of the Union list which is not liable to have an effect on human health, since its impact on the overall exposure to polysorbates (E 432-436) is negligible. Consequently, it is not necessary to seek the opinion of the Authority.
- (10) For the sake of consistency, it is appropriate to address the requested use of (polysorbate 65) (E 436) by authorising the group polysorbates (E 432-436) in the respective food categories.
- (11) Therefore, it is appropriate to authorise the use of polysorbates (E 432-436) at the maximum level of 10 mg/kg in the food categories 14.1.4 'Flavoured drinks', 14.2.3 'Cider and perry', 14.2.4 'Fruit wine and made wine' and 14.2.8 'Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol'.
- (12) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 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 March 2020.

For the Commission The President Ursula VON DER LEYEN

<sup>(\*)</sup> http://www.efsa.europa.eu/en/applications/foodingredients/tools

5.3.2020

Part E of Annex II to Regulation (EC) No 1333/2008 is amended as follows:

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(1) in food category 14.1.4 'Flavoured drinks', the following new entry for polysorbates (E 432-436) is inserted after the entry for soybean hemicellulose (E 426):

'E 432-436 Polysorbates	10 (1)	only carbonated drinks'
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(2) in food category 14.2.3 'Cider and perry', the following new entry for polysorbates (E 432-436) is inserted after the entry for propane-1, 2-diol alginate (E 405):

·]	E 432-436	Polysorbates	10	(1)	only carbonated drinks'
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(3) in food category 14.2.4 'Fruit wine and made wine', the following new entry for polysorbates (E 432-436) is inserted after the entry for metatartaric acid (E 353):

'E 432-43	Polysorbates	10	(1)	only carbonated drinks'
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(4) in food category 14.2.8 'Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol', the following new entry for polysorbates (E 432-436) is inserted after the entry for propane-1, 2-diol alginate (E 405):

	'E 432-436	Polysorbates	10	(1)	only carbonated drinks'
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## COMMISSION IMPLEMENTING REGULATION (EU) 2020/357

## of 4 March 2020

## amending Regulation (EU) 2018/395 as regards balloon pilot licences

## (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 (<sup>1</sup>), and in particular Articles 23, 27 and 31 thereof,

Whereas:

- (1) The Commission is to adopt the necessary implementing rules for establishing the requirements for balloon pilot licences ('BPLs') in accordance with Regulation (EU) 2018/1139, where such aircraft meet the conditions specified in points (b)(i) and (ii) of Article 2(1) of that Regulation.
- (2) In light of the specific nature of flight crew licensing for balloons, dedicated licensing requirements that are laid down in stand-alone regulations are necessary. Those requirements should be based on the general rules for flight crew licensing that are laid down in Commission Regulation (EU) No 1178/2011 (<sup>2</sup>). However, they should be restructured and simplified in order to ensure that they are proportionate and founded on a risk-based approach, whilst ensuring that balloon pilots are and continue to be competent to carry out their activities and to discharge their responsibilities.
- (3) Pursuant to Article 12(2a)(3) of Regulation (EU) No 1178/2011, Member States may continue to apply national licensing rules that provide access to basic pilot privileges until 8 April 2020. Some Member States have reported to the Commission and the European Union Aviation Safety Agency ('EASA') that, in that context, continuation of those national licensing rules, whereby student pilots exercise limited privileges without supervision and obtain basic privileges on a step-by-step basis supports the promotion of aerial sports and recreational activities due to easy and more affordable access to flying. Promoting and enabling such easier access to general aviation is in line with the objectives of EASA's General Aviation Road Map that aims to create a more proportional, flexible and proactive regulatory system (<sup>3</sup>). For those reasons, Member States should be given the discretion to continue with those national licensing rules in accordance with the principles introduced in Regulation (EU) (<sup>4</sup>) for the purpose of issuing balloon pilot licences ('BPL'). However, Member States should also monitor the use of such authorisations. The Member States should also monitor the use of such authorisation is acceptable level of aviation safety.

<sup>(&</sup>lt;sup>1</sup>) OJ L 212, 22.8.2018, p. 1.

<sup>(2)</sup> Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p. 1).

<sup>(3)</sup> https://www.easa.europa.eu/easa-and-you/general-aviation/general-aviation-road-map

<sup>(\*)</sup> Commission Regulation (EU) 2019/430 of 18 March 2019 amending Regulation (EU) No 1178/2011 as regards the exercise of limited privileges without supervision before the issuance of a light aircraft pilot licence (OJ L 75 19.3.2019 p. 66).

- (4) In order to ensure a smooth transition, any certificates, authorisations and approvals issued to balloon pilots in accordance with Regulation (EU) No 1178/2011 prior to the date of application of this Regulation should continue to be valid. National balloon pilot licences issued prior to the date of application of this Regulation should be converted into licences issued in accordance with this Regulation, through conversion reports established by the competent authorities of Member States in consultation with the EASA.
- (5) Balloon pilot trainings that commenced in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 prior to the date of application of this Regulation, should be fully credited because they provide equal or even broader scope of training requirements than those introduced by this Regulation. Training that commenced prior to the date of application of this Regulation in accordance with Annex 1 to the Chicago Convention should be credited on the basis of credit reports established by the Member States.
- (6) Existing training organisations should be given the appropriate time to adapt their training programmes, where necessary, in the context of the simplified training requirements.
- (7) Provisions of Commission Regulation (EU) 2018/395 <sup>(5)</sup> should be updated also as regards operations with balloons, to take account of lessons learned since the adoption of that regulation and to clarify certain aspects, such as the submission of declarations for commercial activities.
- (8) The measures provided for in this Regulation are based on Opinion No 01/2019 (<sup>6</sup>) of the EASA in accordance with points (b) and (c) of Article 75(2) and with Article 76(1) of Regulation (EU) 2018/1139.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 127 of Regulation (EC) No 2018/1139,

HAS ADOPTED THIS REGULATION:

#### Article 1

Regulation (EU) 2018/395 is amended as follows:

(1) the title is replaced by the following:

'Commission Regulation (EU) 2018/395 of 13 March 2018 laying down detailed rules for the operation of balloons as well as for the flight crew licensing for balloons pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council';

- (2) in Article 1, paragraph 1 is replaced by the following:
  - <sup>(1)</sup> This Regulation lays down detailed rules for air operations with balloons as well as for issuing and maintaining pilot licences and associated ratings, privileges and certificates for balloons, where such aircraft meet the conditions laid down in points (b)(i) and (ii) of Article (2)(1) of Regulation (EU) 2018/1139 of the European Parliament and of the Council (\*).

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

<sup>(5)</sup> Commission Regulation (EU) 2018/395 of 13 March 2018 laying down detailed rules for the operation of balloons pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 71, 14.3.2018, p. 10).

<sup>(°)</sup> Easier access for GA pilots to IFR flying & Revision of the balloon and sailplane licensing requirements, (Opinion No 01/2019 (A) & (B), 19.02.2019), available at: https://www.easa.europa.eu/document-library/opinions

- (3) Article 2 is amended as follows:
  - (a) the introductory sentence is replaced by the following:

For the purpose of this Regulation, the following definitions and, unless terms are defined otherwise in this Article, the definitions of Article 2 of Commission Regulation (EU) No 1178/2011 (\*) apply:

- (\*) Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p. 1).';
- (b) the following point (7a) is inserted:
  - (7a) "commercial operation" means any operation of a balloon, in return for remuneration or other valuable consideration, which is available for the public or, when not made available to the public, is performed under a contract between an operator and a customer, where the latter has no control over the operator;"
- (c) point (10) is replaced by the following:
  - '(10) "introductory flight" means any air operation, against remuneration or other valuable consideration, that consists of an air tour of short duration for the purpose of attracting new trainees or new members, performed either by a training organisation referred to in Article 10a of Regulation (EU) No 1178/2011 or by an organisation established with the aim of promoting aerial sport or leisure aviation;';
- (d) point (12) is replaced by the following:
  - '(12) "dry lease agreement" means an agreement between undertakings pursuant to which the balloon is operated under the responsibility of the lessee;';
- (e) the following points (13) to (15) are added:
  - '(13) "national licence" means a pilot licence issued by a Member State in accordance with national legislation before the date of application of Annex III (Part-BFCL) to this Regulation or of Annex I (Part-FCL) to Regulation (EU) No 1178/2011;
  - (14) "Part-BFCL licence" means a flight crew licence which complies with the requirements of Annex III (Part-BFCL) to this Regulation;
  - (15) "conversion report" means a report on the basis of which a licence may be converted into a Part-BFCL licence.';
- (4) paragraph 2 of Article 3 is amended as follows:
  - (a) the first subparagraph is replaced by the following:
    - <sup>2</sup>. Operators of balloons shall engage in commercial operations only after having declared to the competent authority their capacity and means to discharge the responsibilities associated with the operation of the balloon.';
  - (b) the second subparagraph is deleted;
  - (c) the third subparagraph is amended as follows:
    - (i) the introductory sentence is replaced by the following:

'The first subparagraph shall not apply to the following operations with balloons:';

- (ii) points (c) and (d) are replaced by the following:
  - (c) introductory flights with four individuals or less, including the pilot, and flights for the purposes of parachute dropping, performed either by a training organisation referred to in Article 10a of Regulation (EU) No 1178/2011 that has its principal place of business in a Member State, or by an organisation created for the purposes of promoting aerial sport or leisure aviation, provided that the organisation operates the balloon on the basis of either ownership or a dry lease agreement and provided that the flight does not generate profits distributed outside the organisation and that such flights represent only a marginal activity of the organisation;
  - (d) training flights performed by a training organisation referred to in Article 10a of Regulation (EU) No 1178/2011 that has its principal place of business in a Member State.';

(5) after Article 3, the following Articles 3a to 3d are inserted:

#### 'Article 3a

# Pilot licences and medical certification

- 1. Without prejudice to Commission Delegated Regulation (EU) (\*), pilots of aircraft referred to in Article 1(1) of this Regulation shall comply with the technical requirements and administrative procedures laid down in Annex III (Part-BFCL) to this Regulation and in Annex IV (Part-MED) to Regulation (EU) No 1178/2011.
- 2. As an exception to the privileges of the holders of licences as defined in Annex III (Part-BFCL) to this Regulation, holders of such licences may carry out flights referred to in Article 3(2)(a) to (d) without complying with point BFCL.215 of Annex III (Part-BFCL) to this Regulation.
- 3. A Member State may authorise student pilots who follow a balloon pilot licence ("BPL") training course to exercise limited privileges without supervision before they meet all the requirements that are necessary for the issue of a BPL in accordance with Annex III (Part-BFCL), subject to all of the following conditions:
  - (a) the scope of the privileges granted shall be based on a safety risk assessment carried out by the Member State, taking into account the extent of training necessary for the intended level of pilot competence to be achieved;
  - (b) the privileges shall be limited to the following:
    - (i) the whole or part of the national territory of the authorising Member State;
    - (ii) balloons that are registered in the authorising Member State;
  - (c) the holder of such an authorisation who applies for the issue of a BPL shall receive credits for training conducted under the authorisation on the basis of a recommendation from an approved training organisation ("ATO") or a declared training organisation ("DTO");
  - (d) the Member State shall submit reports and safety risk assessments to the Commission and the European Union Aviation Safety Agency every 3 years;
  - (e) the Member State shall monitor the use of authorisations issued under this paragraph to ensure an acceptable level of aviation safety and take appropriate action in case of identifying an increased safety risk or any safety concerns.

#### Article 3b

#### Existing pilot licences and national medical certificates

- 1. Part-FCL licences for balloons and associated privileges, ratings and certificates issued by a Member State before the date of application of this Regulation shall be deemed to have been issued in accordance with this Regulation. Member States shall replace those licences with licences that comply with the format laid down in Annex VI (Part-ARA) to Regulation (EU) No 1178/2011 when they reissue licences for administrative reasons or upon a request of licence holders.
- 2. When a Member State reissues licences and associated privileges, ratings and certificates in accordance with paragraph 1 of this Article, the Member State shall, as applicable:
  - (a) transfer all privileges already endorsed in Part-FCL licences to the new licence format;
  - (b) convert the privileges for tethered flight or commercial operation associated with a Part-FCL licence into a tethered flight rating or a commercial operation rating in accordance with the provisions of Point BFCL.200 and BFCL.215 of Annex III (Part-BFCL) to this Regulation;
  - (c) endorse the expiry date of a flight instructor certificate associated with a Part-FCL licence into the pilot's logbook or issue an equivalent document. After that date, those pilots shall exercise instructor privileges only if they comply with point BFCL.360 of Annex III (Part-BFCL) to this Regulation.
- 3. Holders of national licences for balloons issued by a Member State before the date of application of Annex III (Part-BFCL) to this Regulation shall be allowed to continue to exercise the privileges of their licences until 8 April 2021. By that date, Member States shall convert those licences into Part-BFCL licences and associated ratings, privileges and certificates in accordance with the elements laid down in a conversion report that complies with the requirements of Article 4(4) and (5) of Regulation (EU) No 1178/2011.

4. National pilot medical certificates associated with a licence as specified in paragraph 2 of this Article and issued by a Member State before the date of application of Annex III (Part-BFCL) to this Regulation shall remain valid until the date of their next revalidation or until 8 April 2021, whichever is the earliest. The revalidation of those medical certificates shall comply with the requirements of Annex IV (Part-MED) to Regulation (EU) No 1178/2011.

Article 3c

# Credit for training that commenced prior to the date of application of this Regulation

- 1. In respect of issuing Part-BFCL licences and associated privileges, ratings or certificates in accordance with Annex III (Part-BFCL) to this Regulation, training that commenced prior to the date of application of this Regulation in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 shall be deemed to comply with the requirements of this Regulation, provided that the BPL is issued by 8 April 2021 at the latest. In that case, the following shall apply:
  - (a) BPL training commenced on balloons representing the hot-air airship class, including the related testing, may be completed on those balloons;
  - (b) training hours completed in the hot-air balloon class in balloons other than group A of that balloon class shall be fully credited towards the requirement in point BFCL.130(b) of Annex III.
- 2. Training that commenced prior to the date of application of this Regulation or of Annex I (Part-FCL) to Regulation (EU) No 1178/2011, in accordance with Annex 1 to the Chicago Convention, shall be credited for the purposes of issuing Part-BFCL licences on the basis of a credit report established by the Member State in consultation with the European Union Aviation Safety Agency.
- 3. The credit report referred to in paragraph 2 shall describe the scope of the training, indicate for which requirements of Part-BFCL credit is given and, if applicable, which requirements applicants need to comply with in order to be issued with a Part-BFCL licence. It shall include copies of all the documents necessary to attest the scope of the training, as well as copies of the national regulations and procedures in accordance with which the training was initiated.

Article 3d

# **Training organisations**

- 1. Training organisations for pilot licences referred to in Article 1(1) shall comply with the requirements of Article 10a of Regulation (EU) No 1178/2011.
- 2. Training organisations referred to in paragraph 1 of this Article which hold an approval issued in accordance with Annex VII (Part-ORA) to Regulation (EU) No 1178/2011 or have submitted a declaration in accordance with Annex VIII (Part-DTO) to Regulation (EU) No 1178/2011 before the date of application of this Regulation shall adapt their training programmes, where necessary, by 8 April 2021 at the latest.

- (6) Annex I (Part-DEF) is amended in accordance with Annex I to this Regulation;
- (7) Annex II (Part-BOP) is amended in accordance with Annex II to this Regulation;
- (8) Annex III (Part-BFCL) is added as set out in Annex III to this Regulation.

Article 2

<sup>(\*)</sup> Commission Delegated Regulation (EU) of 4 March 2020 (not yet published in the Official Journal).";

It shall apply from 8 April 2020.

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

Done at Brussels, 4 March 2020.

For the Commission The President Ursula VON DER LEYEN

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# ANNEX I

Annex I 'Definitions' (Part-DEF) to Regulation (EU) 2018/395 is amended as follows:

(1) the introductory sentence is replaced by the following:

For the purpose of this Regulation, the following definitions and, unless terms are defined otherwise in this Annex, the definitions of Article 2 of Regulation (EU) No 1178/2011 as well as of point FCL.010 of Annex I (Part-FCL) to that Regulation, shall apply:';

- (2) points 1 and 2 are replaced by the following:
  - "acceptable means of compliance (AMC)" means non-binding standards adopted by the Agency to illustrate means to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts;
  - "alternative means of compliance (AltMoC)" means those means that propose an alternative to an existing AMC or those that propose new means to establish compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts for which no associated AMC have been adopted by the Agency;';
- (3) the following point 11a is inserted:
  - '11a. "flight time" means the total time from the moment the basket leaves the ground for the purpose of taking off until the moment it finally comes to a rest at the end of the flight;';
- (4) the following points 17a and 17b are inserted:
  - '17a. "class of balloons" means a categorisation of balloons taking into account the lifting means used to sustain flight;
  - 17b. "proficiency check" means the demonstration of skill for the purpose of complying with the recency requirements as established in this Regulation, including oral examinations as may be required;';
- (5) point 22 is replaced by the following:

'22. "group of balloons" means a categorisation of balloons, taking into account the size or capacity of the envelope;';

- (6) the following points 23 to 26 are added:
  - '23. "skill test" means the demonstration of skill for the purpose of issuing a licence or rating, or extension of a privilege, including oral examinations as may be required;
  - 24. "assessment of competence" means the demonstration of skill, knowledge and attitude for the initial issue, revalidation or renewal of an instructor or examiner certificate;
  - 25. "solo flight" means a flight during which a student pilot is the sole occupant of the balloon;
  - 26. "tethered flight" means a flight with a tether system that anchors the balloon to a fixed location during operation, with the exception of a tether which may be used as part of the take-off procedure.'

# ANNEX II

Annex II 'Balloon Air Operations' (Part-BOP) to Regulation (EU) 2018/395 is amended as follows:

- (1) in point BOP.BAS.010, paragraph (a) is replaced by the following:
  - '(a) An operator shall, when so requested by the competent authority which verifies continued compliance by the operator in accordance with point ARO.GEN.300(a)(2) of Annex II (Part-ARO) to Regulation (EU) No 965/2012, demonstrate compliance with the essential requirements set out in Annex V to Regulation (EU) 2018/1139 and with the requirements of this Regulation.';
- (2) point BOP.BAS.020 is replaced by the following:

## 'BOP.BAS.020 Immediate reaction to a safety problem

The operator shall implement:

- (a) safety measures mandated by the competent authority in accordance with paragraph (c) of point ARO.GEN.135 of Annex II (Part-ARO) to Regulation (EU) No 965/2012; and
- (b) airworthiness directives and other mandatory information issued by the Agency in accordance with paragraph (h) of Article 77(1) of Regulation (EU) 2018/1139.';
- (3) point BOP.BAS.025 is replaced by the following:

#### 'BOP.BAS.025 Designation as pilot-in-command

The operator shall designate a pilot-in-command who is qualified to act as pilot-in-command in accordance with Annex III (Part-BFCL) to this Regulation.';

- (4) in point BOP.BAS.300, paragraph (c) is replaced by the following:
  - (c) Instruments and equipment not required by this Section, as well as any other equipment that is not required by this Annex but is carried on board a balloon during a flight, shall comply with the following two conditions:
    - the information provided by those instruments or equipment shall not be used by the flight crew to comply with the essential requirements for airworthiness set out in Annex II to Regulation (EU) 2018/1139;
    - (2) the instruments and equipment shall not affect the airworthiness of the balloon, even in the case of failures or malfunction.';
- (5) in point BOP.ADD.005, paragraph (a) is replaced by the following:
  - '(a) The operator shall be responsible for the operation of the balloon in accordance with the essential requirements set out in Annex V to Regulation (EU) 2018/1139, with the requirements of this Subpart and with its declaration.';
- (6) in point BOP.ADD.015, paragraph (a) is replaced by the following:
  - '(a) For the purpose of determining compliance with the essential requirements set out in Annex V to Regulation (EU) 2018/1139 and with the requirements of this Regulation, the operator shall grant access to any person authorised by the competent authority at any time to any facility, balloon, document, records, data, procedures or any other material relevant to the operator's activity that falls within the scope of this Regulation, irrespective of whether or not the activity is contracted.';
- (7) point BOP.ADD.035 is replaced by the following:

#### 'BOP.ADD.035 Contracted activities

When contracting any part of its activity that falls within the scope of this Regulation, the operator shall be responsible for ensuring that the contracted organisation carries out the activity in accordance with the essential requirements set out in Annex V to Regulation (EU) 2018/1139 and with the requirements of this Regulation. The operator shall also ensure that the competent authority is given access to the contracted organisation in order to determine that the operator complies with those requirements.';

- (8) in point BOP.ADD.040, paragraph (a) is replaced by the following:
  - '(a) The operator shall appoint an accountable manager who has the authority to ensure that all activities that fall within the scope of this Regulation can be financed and carried out in accordance with the essential requirements set out in Annex V to Regulation (EU) 2018/1139 and with the requirements of this Regulation. The accountable manager shall be responsible for establishing and maintaining an effective management system.';

(9) point BOP.ADD.045 is replaced by the following:

# 'BOP.ADD.045 Facility requirements

The operator shall have facilities that are sufficient to allow the performance and management of all tasks and activities required to ensure compliance with the essential requirements set out in Annex V to Regulation (EU) 2018/1139 and with the requirements of this Regulation.';

- (10) in point BOP.ADD.100, paragraph (a) is replaced by the following:
  - '(a) In the declaration referred to in the second subparagraph of Article 3(2), the operator shall confirm that it complies and will continue to comply with the essential requirements set out in Annex V to Regulation (EU) 2018/1139 and with the requirements of this Regulation.';
- (11) in point BOP.ADD.105, paragraph (a) is replaced by the following:
  - (a) The operator shall notify the competent authority without delay of 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 this Regulation, as declared to the competent authority, and of any changes in respect of the information referred to in point BOP.ADD.100(b) and the list of AltMoCs referred to in point BOP.ADD.100(c), as included in or annexed to the declaration.';
- (12) in point BOP.ADD.115, paragraph (c) is replaced by the following:
  - '(c) Where a balloon registered in a third country is subject to a dry lease agreement, the operator of such balloon shall ensure compliance with the essential requirements relating to continuing airworthiness set out in Annexes II and V to Regulation (EU) 2018/1139 and with the requirements of this Regulation.';
- (13) in point BOP.ADD.300, paragraph (c) is replaced by the following:
  - (c) All flight crew members shall hold a licence and ratings issued or accepted in accordance with Annex III to this Regulation and shall be appropriate to the duties assigned to them.';
- (14) in point BOP.ADD.300, paragraph (e) is replaced by the following:
  - (e) When engaging the services of flight crew members who work on a freelance or part-time basis, the operator shall verify that all of the following requirements are complied with:
    - (1) the requirements of this Subpart;
    - (2) Annex III to this Regulation, including the requirements on recent experience;
    - (3) the flight and duty time limitations and rest requirements in accordance with the national law of the Member State where the operator has its principal place of business, taking into account all services rendered by the flight crew member to other operators.';
- (15) in point BOP.ADD.305, paragraph (b) is replaced by the following:
  - (b) The operator shall only designate a pilot to act as pilot-in-command if he or she:
    - (1) is qualified to act as pilot-in-command in accordance with Annex III to this Regulation;
    - (2) has the minimum level of experience specified in the operations manual; and
    - (3) has adequate knowledge of the area to be flown.';
- (16) point BOP.ADD.310 is replaced by the following:

# 'BOP.ADD.310 Provision of training and checking

All training and checking of flight crew members required pursuant to point BOP.ADD.315 shall be provided as follows:

- (a) in accordance with the training programmes and syllabi established by the operator in the operations manual;
- (b) by appropriately qualified persons and, as regards flight training and checking, by persons qualified in accordance with Annex III to this Regulation.';

(17) the Appendix is replaced by the following:

'Appendix

		DECLARA	TION	
	in accordance	with Commission	Regulation (EU) 2018/39	95
-	perator has its principal pla t details of the accountable			
Balloon operatio	n			
Starting date of co	ommercial operation and, v	vhere relevant, dat	e of change to existing co	mmercial operation.
Information on ba	alloon(s) used, commercial	operation(s) and c	ontinuing airworthiness i	management: (1)
Balloon type	Balloon registration	Main base	Type(s) of opera- tion ( <sup>2</sup> )	Continuing airworthi- ness management organi- sation ( <sup>3</sup> )
Where applicable, <b>Statements</b>	list of the AltMoCs with re	eferences to the as	sociated AMC (annex to t	his declaration):
(EU) 2018/1139 a In particular, the c ADD of Annex II	and with the requirements of operator conducts its comm to Regulation (EU) 2018/3 nt system documentation, ts will be carried out in acc	of Regulation (EU) hercial operations 95: including the oper	2018/395. in accordance with the for rations manual, comply w	set out in Annex V to Regulation llowing requirements of Subpar rith the requirements of Subpar ons manual as required by point
No 748/2012 or 1 country and are su	erated either have a certific meet the specific airworthin ubject to a wet lease agreem (c) of Subpart ADD.	ness requirements	applicable to balloons the	
	members hold a licence and ired by point BOP.ADD.30			rith Annex III to Regulation (EU
essential requirem 2018/395 as decla	ents set out in Annex V to	Regulation (EU) 2 ority through this	018/1139 and with the redeclaration and any chan	ecting its compliance with the equirements of Regulation (EU) ges to the information and lists 105(a) of Subpart ADD.
□ The operator co	onfirms that all information	n included in this c	leclaration, including its a	nnexes, is complete and correct
Date, name and si	gnature of the accountable	manager'		
and signed. ( <sup>2</sup> ) "Type(s) of opera ( <sup>3</sup> ) Information abo	tion" refers to the type(s) of co	ommercial operation ble for the continu	conducted with the balloon.	rate annex. The annex shall be date hent shall include the name of th

#### ANNEX III

# 'ANNEX III

# **REQUIREMENTS FOR BALLOON FLIGHT CREW LICENSING**

# [PART-BFCL]

#### SUBPART GEN

## GENERAL REQUIREMENTS

## BFCL.001 Scope

This Annex establishes the requirements for the issue of a balloon pilot licence ("BPL") and associated privileges, ratings and certificates, and the conditions for their validity and use.

# **BFCL.005** Competent authority

For the purpose of this Annex, the competent authority shall be an authority designated by the Member State to which a person applies for the issue of a BPL or associated privileges, ratings or certificates.

# BFCL.010 Classes and groups of balloons

For the purpose of this Annex, balloons shall be categorised in the following classes and groups:

- (a) "hot-air balloon" class:
  - (1) group A: envelope capacity up to 3 400 m<sup>3</sup> (120 069 ft<sup>3</sup>);
  - (2) group B: envelope capacity between 3 401 m<sup>3</sup> (120 070 ft<sup>3</sup>) and 6 000 m<sup>3</sup> (211 888 ft<sup>3</sup>);
  - (3) group C: envelope capacity between 6 001 m<sup>3</sup> (211 889 ft<sup>3</sup>) and 10 500 m<sup>3</sup> (370 804 ft<sup>3</sup>);
  - (4) group D: envelope capacity of more than 10 500 m<sup>3</sup> (370 804 ft<sup>3</sup>);
- (b) "gas balloon" class;
- (c) "mixed balloon" class;
- (d) "hot-air airship" class.

# BFCL.015 Application for and issue, revalidation and renewal of a BPL as well as associated privileges, ratings and certificates

- (a) An application for the following shall be submitted to the competent authority in a form and manner established by that competent authority:
  - (1) the issue of a BPL and associated ratings;
  - (2) the extension of the privileges of a BPL;
  - (3) the issue of a flight instructor (for balloons) ("FI(B)") certificate;
  - (4) the issue, revalidation and renewal of a flight examiner (for balloons) ("FE(B)") certificate; and
  - (5) any amendments to the BPL and associated privileges, ratings certificates.
- (b) An application specified in paragraph (a) shall be accompanied by evidence that the applicant complies with the relevant requirements established in this Annex and in Annex IV (Part-MED) to Regulation (EU) No 1178/2011.
- (c) Any limitation or extension of the privileges granted by a licence, rating or certificate shall be endorsed on the licence or certificate by the competent authority.
- (d) A person shall not hold at any time more than one BPL issued in accordance with this Annex.
- (e) A licence holder shall submit applications as specified in paragraph (a) to the competent authority designated by the Member State in which any of his or her licences was issued in accordance with this Annex (Part-BFCL), or Annex I (Part-FCL) to Regulation (EU) No 1178/2011 or Annex III (Part-SFCL) to Implementing Regulation (EU) 2018/1976, as applicable.

- (f) A BPL holder may apply for a change of competent authority to the competent authority designated by another Member State but in such case the new competent authority shall be the same for all the licences held.
- (g) Applicants shall apply for the issue of a BPL and associated ratings, privileges or certificates not later than 6 months after having successfully completed the skill test or assessment of competence.

#### **BFCL.030 Practical skill test**

Except for the skill test for the commercial operation rating as specified in point BFCL.215, an applicant for a skill test shall be recommended for the test by the ATO or the DTO that is responsible for the training undertaken by the applicants, once the training is completed. The training records shall be made available to the examiner by the ATO or DTO.

# BFCL.035 Crediting of flight time

Applicants for a BPL or an associated privilege, rating or certificate shall be fully credited with all solo, dual instruction or PIC flight time on balloons towards the requirement of a total flight time for the licence, privilege, rating or certificate.

#### BFCL.045 Obligation to carry and present documents

- (a) When exercising the privileges of BPL licence, BPL holders shall carry all of the following:
  - (1) a valid BPL;
  - (2) a valid medical certificate;
  - (3) a personal identification document containing his or her photo;
  - (4) sufficient logbook data to demonstrate compliance with the requirements of this Annex.
- (b) Student pilots shall carry on all solo flights:
  - (1) the documents as specified in paragraphs (a)(2) and (a)(3); and
  - (2) evidence of the authorisation required by point BFCL.125(a).
- (c) BPL holders or student pilots shall without undue delay present the documents as specified in paragraph (a) or (b) for inspection upon request by an authorised representative of the competent authority.

## **BFCL.050** Recording of flight time

BPL holders and student pilots shall keep a reliable record of the details of all flights flown in a form and manner established by the competent authority.

## BFCL.065 Curtailment of privileges of BPL holders aged 70 years or older in commercial passenger ballooning

BPL holders who have attained the age of 70 years shall not act as pilots of a balloon engaged in commercial passenger balloon operations.

# BFCL.070 Limitation, suspension or revocation of licences, privileges, ratings and certificates

- (a) A BPL as well as associated privileges, ratings and certificates issued in accordance with this Annex may be limited, suspended or revoked by the competent authority in accordance with the conditions and procedures laid down in Annex VI (Part-ARA) to Regulation (EU) No 1178/2011 if a BPL holder does not comply with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139 or with the requirements of this Annex as well as of Annex II (Part-BOP) to this Regulation or of Annex IV (Part-MED) to Regulation (EU) No 1178/2011.
- (b) BPL holders shall immediately return the licence or certificate to the competent authority if their licence, privilege, rating or certificate has been limited, suspended or revoked..

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# SUBPART BPL

# BALLOON PILOT LICENCE ("BPL")

# BFCL.115 BPL - Privileges and conditions

(a) The privileges of a BPL holder are to act as PIC in balloons:

- (1) without remuneration in non-commercial operations;
- (2) in commercial operations if he or she holds a commercial operation rating in accordance with point BFCL.215 of Subpart ADD of this Annex.
- (b) By way of derogation from paragraph (a)(1), a BPL holder who has instructor or examiner privileges may receive remuneration for:
  - (1) the provision of flight instruction for the BPL;
  - (2) the conduct of skill tests and proficiency checks for the BPL;
  - (3) the training, testing and checking for the privileges, ratings and certificates attached to a BPL.
- (c) BPL holders shall exercise BPL privileges only if they comply with the applicable recency requirements and only if their medical certificate, appropriate to the privileges exercised, is valid.

# BFCL.120 BPL – Minimum age

Applicants for a BPL shall be at least 16 years of age.

# BFCL.125 BPL – Student pilot

- (a) Student pilots shall not fly solo unless authorised to do so and supervised by a flight instructor for balloons (FI(B)).
- (b) Student pilots shall be at least 14 years of age to be allowed on solo flights.

# BFCL.130 BPL – Training course and experience requirements

Applicants for a BPL shall complete a training course at an ATO or a DTO. The course shall be tailored to the privileges sought and shall include:

- (a) theoretical knowledge as specified in point BFCL.135(a);
- (b) at least 16 hours of flight instruction in either hot-air balloons that represent group A of that class, or gas balloons, including at least:
  - (1) 12 hours of dual flight instruction;
  - (2) 10 inflations and 20 take-offs and landings; and
  - (3) One supervised solo flight with a flight time of at least 30 minutes.

# BFCL.135 BPL – Theoretical knowledge examination

(a) Theoretical knowledge

Applicants for a BPL shall demonstrate a level of theoretical knowledge that is appropriate to the privileges sought through examinations on the following:

- (1) common subjects:
  - (i) air law;
  - (ii) human performance;
  - (iii) meteorology;
  - (iv) communications; and
- (2) specific subjects concerning balloons:
  - (i) principles of flight;
  - (ii) operational procedures;

- (iii) flight performance and planning;
- (iv) aircraft general knowledge related to balloons; and
- (v) navigation.
- (b) Responsibilities of the applicant
  - The applicant shall take the entire set of theoretical knowledge examinations for the BPL under the responsibility of the same Member State's competent authority.
  - (2) The applicant shall take the theoretical knowledge examination only if recommended by the ATO or the DTO that is responsible for his or her training and once he or she has completed the appropriate elements of the training course of theoretical knowledge instruction to a satisfactory standard.
  - (3) The recommendation by the ATO or the DTO shall be valid for 12 months. If the applicant has failed to take at least one theoretical knowledge examination paper within this validity period, the need for further training shall be determined by the ATO or the DTO, based on the needs of the applicant.
- (c) Pass standards
  - (1) A pass in a theoretical knowledge examination paper shall be awarded to the applicant if he or she has achieved at least 75 % of the marks allocated to that paper. No penalty marking shall be applied.
  - (2) Unless otherwise specified in this Annex, an applicant is considered to have successfully completed the required theoretical knowledge examination for the BPL if he or she has passed all the required theoretical knowledge examination papers within a period of 18 months counted from the end of the calendar month when the applicant first attempted to take the examination.
  - (3) If an applicant has failed to pass one of the theoretical knowledge examination papers within four attempts or has failed to pass all papers within the period mentioned in paragraph (2), he or she shall retake the complete set of theoretical knowledge examination papers.
  - (4) Before retaking the theoretical knowledge examinations, the applicant shall undertake further training at an ATO or a DTO. The ATO or the DTO shall determine the extent and scope of the training, based on the needs of the applicant.
- (d) Validity period

The theoretical knowledge examination shall be valid for a period of 24 months counted from the day when the applicant successfully completed the theoretical knowledge examination, in accordance with paragraph (c)(2).

## BFCL.140 BPL - Crediting of theoretical knowledge

Applicants for the issue of a BPL shall be credited towards the theoretical knowledge requirements for the common subjects as specified in point BFCL.135(a)(1) if they:

- (a) hold a licence in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 or Annex III (Part-SFCL) to Implementing Regulation (EU) 2018/1976; or
- (b) have passed the theoretical knowledge examinations for a licence as specified in paragraph (a), as long as this is done within the validity period specified in point BFCL.135(d).

## BFCL.145 BPL - Practical skill test

- (a) Applicants for a BPL shall demonstrate through the completion of a skill test the ability to perform, as PIC on a balloon, the relevant procedures and manoeuvres with competency appropriate to the privileges sought.
- (b) Applicants shall complete the skill test in the same class of balloons in which the training course has been completed in accordance with point BFCL.130 and, in case of hot-air balloons, in a balloon that represents group A of that class.
- (c) To take a skill test for the issue of a BPL, the applicant shall first pass the required theoretical knowledge examination.
- (d) Pass standards
  - (1) The skill test shall be divided into different sections, representing all the different phases of a balloon flight.
  - (2) Failure in any item of a section shall cause the applicant to fail the entire section. If the applicant fails in only one section, he or she shall repeat only that section. Failure in more than one section shall require the applicant to retake the entire test.

- (3) If the applicant needs to retake the test in accordance with paragraph (2) and fails in any section, including those sections that have been passed at a previous attempt, the applicant shall retake the entire test.
- (e) If the applicant fails to achieve a pass in all sections of the test within two attempts, he or she shall receive further practical training.

## BFCL.150 BPL - Extension of privileges to another balloon class or group

- (a) The privileges of the BPL shall be limited to the class of balloon in which the skill test as specified in point BFCL.145 was taken, and, in the case of hot-air balloons, to group A of that class.
- (b) In the case of hot-air balloons, the privileges of the BPL shall be extended to another group within the hot-air balloon class upon application if a pilot has completed at least:
  - (1) two instruction flights with an FI(B) on a balloon of the relevant group;
  - (2) the following amount of hours of flight time as PIC on balloons:
    - (i) at least 100 hours, if privileges for group B balloons are sought;
    - (ii) at least 200 hours, if privileges for group C balloons are sought;
    - (iii) at least 300 hours, if privileges for group D balloons are sought.
- (c) Except for the mixed balloon class, the privileges of the BPL shall be extended to another balloon class, or, if privileges for the hot-air balloon class are sought, to group A of the hot-air balloon class, upon application if a pilot has completed in the relevant balloon class and group:
  - (1) a training course at an ATO or a DTO, including at least:
    - (i) five dual instructional flights; or
    - (ii) in the case of an extension from hot-air balloons to hot-air airships, five hours of dual instruction time; and
  - (2) a skill test during which the pilot has demonstrated to the FE(B) an adequate level of theoretical knowledge for the other class in the following subjects:
    - (i) principles of flight;
    - (ii) operational procedures;
    - (iii) flight performance and planning;
    - (iv) aircraft general knowledge with regard to the balloon class for which the extension of privileges is sought.
- (d) The completion of the training as specified in paragraphs (b)(1) and (c)(1) shall be entered in the logbook of the pilot and signed by:
  - (1) in the case of paragraph (b)(1), the instructor who is responsible for the instruction flights; and
  - (2) in the case of paragraph (c)(1), the head of training of the ATO or of the DTO that is responsible for the training.
- (e) A BPL holder shall exercise his or her privileges in the mixed balloon class only if he or she has privileges for both the hot-air balloon class and the gas balloon class.

## **BFCL.160 BPL – Recency requirements**

- (a) A BPL holder shall only exercise the privileges of his or her licence if he or she has completed in the relevant balloon class:
  - (1) either:
    - (i) within the last 24 months before the planned flight, at least six hours of flight time as PIC, including 10 takeoffs and landings, as PIC or flying dual or solo under the supervision of an FI(B); and
    - (ii) within the last 48 months before the planned flight, at least one training flight with an FI(B); or
  - (2) within the last 24 months before the planned flight, a proficiency check in accordance with point (c).

- (b) In addition to the requirements in paragraph (a), in the case of a pilot who is qualified to fly more than one class of balloons, in order to exercise his or her privileges in the other balloon class or the other balloon classes, he or she shall have completed at least three hours of flight time, as PIC or flying dual or solo under the supervision of an FI(B), on each additional balloon class within the last 24 months.
- (c) A BPL holder who does not comply with the requirements in paragraph (a)(1) and, if applicable, (b), before resuming the exercise of his or her privileges, shall pass a proficiency check with an FE(B) in a balloon that represents the relevant class.
- (d) After complying with paragraph (a), (b) or (c), as applicable, a BPL holder with privileges to fly hot-air balloons shall exercise his or her privileges only on hot-air balloons that represent:
  - (i) the same group of hot-air balloons in which the training flight as specified in paragraph (a)(1)(ii) or the proficiency check as specified in paragraph (c), as applicable, have been completed, or a group with a smaller envelope size; or
  - (ii) group A of hot-air balloons in cases where a pilot, in accordance with paragraph (b), has completed the training flight as specified in paragraph (a)(2) in a balloon class other than hot-air balloons.
- (e) The completion of the dual flights, the flights under supervision and the training flight as specified in paragraph (a)(1) and (b), as well as the proficiency check as specified in paragraph (c) shall be entered in the logbook of the pilot and signed by, in the case of paragraphs (a)(1) and (b), the responsible FI(B) and, in the case of paragraph (c), the responsible FE(B).
- (f) A BPL holder, that holds also the privileges for commercial operations as specified in point BFCL.215 of Subpart ADD of this Annex, shall be deemed to comply with the requirements of:
  - paragraph (a) and, if applicable, (b), in case he or she has completed a proficiency check in accordance with point BFCL.215(d)(2)(i) in the relevant balloon class or classes within the last 24 months; or
  - (2) paragraph (a)(1)(ii), in case he or she has completed the training flight as specified in point BFCL.215(d)(2)(ii) in the relevant balloon class.

In the case of the hot-air balloon class, limitations specified in paragraph (d), concerning the privileges to operate different classes of balloons, shall apply, depending on the balloon class used for complying with paragraphs (f)(1) or (f)(2).

#### SUBPART ADD

# ADDITIONAL RATINGS

#### BFCL.200 Tethered hot-air balloon flight rating

- (a) A BPL holder shall undertake tethered flights with hot-air balloons only if he or she holds a tethered hot-air balloon flight rating in accordance with this point.
- (b) To apply for a tethered hot-air balloon flight rating, the applicant shall:
  - (1) have privileges for the hot-air balloon class;
  - (2) first complete at least two tethered hot-air balloon instruction flights.
- (c) The completion of the tethered hot-air balloon training shall be entered in the logbook and signed by the FI(B) who is responsible for the training.
- (d) A pilot who holds a tethered hot-air balloon flight rating shall exercise his or her privileges only if he or she has completed at least one tethered hot-air balloon flight during the 48 months preceding the planned flight, or, if he or she has not performed such a flight, the pilot shall exercise his or her privileges if they have performed a tethered hotair balloon flight flying dual or solo under the supervision of an FI(B). The completion of such dual or solo flight under supervision shall be entered in the pilots logbook and signed by the FI(B).

# **BFCL.210** Night rating

(a) A BPL holder shall exercise the privileges of his or her licence in VFR conditions at night only if he or she holds a night rating in accordance with this point.

- (b) An applicant for a night rating shall have completed at least two instruction flights at night of at least one hour each.
- (c) The completion of the night rating training shall be entered in the logbook and signed by the FI(B) who is responsible for the training.

# **BFCL.215** Commercial operation rating

- (a) A BPL holder shall exercise the privileges of his or her licence during commercial operations with balloons only if he or she holds a commercial operation rating in accordance with this point.
- (b) An applicant for a commercial operation rating shall:
  - (1) have attained the age of 18 years;
  - (2) have completed 50 hours of flight time and 50 take-offs and landings as PIC on balloons;
  - (3) have the privileges for the class of balloon in which the privileges of the commercial operation rating will be exercised; and
  - (4) have passed a skill test on the relevant class of balloon during which he or she shall demonstrate to an FE(B) the competence required for commercial balloon operations.
- (c) The privileges of the commercial operation rating shall be limited to the class of balloon in which the skill test in accordance with paragraph (b)(3) has been completed. The privileges shall be extended upon application to another class of balloon if, in that other class, the applicant complies with paragraph (b)(3) and (b)(4).
- (d) A pilot who holds a commercial operation rating shall exercise the privileges of that rating in commercial passenger ballooning only if he or she has completed:
  - (1) within the 180 days preceding the planned flight:
    - (i) at least three flights as PIC in balloons, of which at least one shall be in a balloon of the relevant class; or
    - (ii) one flight as PIC in a balloon of the relevant class under the supervision of an FI(B) who is qualified in accordance with this point; and
  - (2) within the 24 months preceding the planned flight:
    - (i) a proficiency check, in a balloon of the relevant class, during which he or she shall demonstrate to an FE(B) the competence required for commercial passenger ballooning; or
    - (ii) a refresher course at an ATO or a DTO, tailored to the competence required for commercial balloon operations, including at least six hours of theoretical knowledge instruction and one training flight in a balloon of the relevant class with an FI(B) who is qualified for commercial balloon operations in accordance with this point.
- (e) To maintain the privileges of the commercial operation rating for all balloon classes, a pilot who holds a commercial operation rating with privileges extended to more than one class of balloons shall comply with the requirements in paragraph (d)(2) in at least one class of balloons.
- (f) A pilot who complies with paragraph (d) and holds a commercial operation rating for the hot-air balloon class shall exercise the privileges of that rating in the hot-air balloon class only on balloons that represent:
  - (i) the same group of the hot-air balloon in which the proficiency check as specified in paragraph (d)(2)(i) or the training flight as specified in paragraph (d)(2)(ii), have been completed; or
  - (ii) a hot-air balloon group with a smaller envelope size.
- (g) The completion of the flight under supervision as specified in paragraph (d)(1)(ii), the proficiency check as specified in paragraph (d)(2)(i) and the refresher training course as specified in paragraph (d)(2)(ii) shall be entered in the logbook of the pilot and shall be signed by the head of training of the ATO or the DTO, or the FI(B) or the FE(B) that is responsible for the training course, the supervision or the proficiency check, as applicable.
- (h) A pilot who has completed an operator proficiency check in accordance with point BOP.ADD.315 of Annex II (Part-BOP) to this Regulation shall be deemed to comply with paragraph (d)(2)(i).

## SUBPART FI

# FLIGHT INSTRUCTORS

#### Section 1

#### **General requirements**

## **BFCL.300 Flight instructor certificates**

(a) General

An instructor shall only carry out flight instruction in a balloon if he or she:

- (1) holds:
  - (i) a BPL including the privileges, ratings and certificates for which flight instruction is to be provided; and
  - (ii) a balloon flight instructor (FI(B)) certificate appropriate to the instruction carried out, and issued in accordance with this Subpart; and
- (2) is entitled to act as PIC in the balloon during flight instruction.
- (b) Instruction provided outside the territory of the Member States
  - (1) By way of derogation from subparagraph (a)(1), in the case of flight instruction provided during a training course approved in accordance with this Annex (Part-BFCL) outside the territory for which Member States are responsible under the Chicago Convention, the competent authority shall issue a flight instructor certificate to an applicant who holds a balloon pilot licence that is compliant with Annex 1 to the Chicago Convention, provided that the applicant:
    - (i) holds at least a licence including, where relevant, privileges, ratings or certificates equivalent to those for which he or she is authorised to instruct;
    - (ii) complies with the requirements established in this Subpart for the issue of the FI(B) certificate with the relevant instructional privileges; and
    - (iii) demonstrates to the competent authority an adequate level of knowledge of European aviation safety rules to be able to exercise his or her instructional privileges in accordance with this Annex.
  - (2) The certificate shall be limited to the provision of approved flight instruction:
    - (i) outside the territory for which Member States are responsible under the Chicago Convention; and
    - (ii) to a student pilot who has sufficient knowledge of the language in which flight instruction is provided.

## Section 2

# Flight instructor certificate for balloons - FI(B)

# BFCL.315 FI(B) certificate - Privileges and conditions

- (a) Subject to compliance of applicants with point BFCL.320 and with the following conditions, an FI(B) certificate shall be issued with privileges to conduct flight instruction for:
  - (1) a BPL;
  - (2) the extension of privileges to further classes and groups of balloons provided that the applicant has completed at least 15 hours of flight time as PIC in each relevant class;
  - (3) a night rating or a tethered flight rating, provided that the applicant has received specific training in providing instruction for the relevant rating at an ATO or at a DTO; and
  - (4) an FI(B) certificate, provided that the applicant has:
    - (i) completed at least 50 hours of flight instruction on balloons; and
    - (ii) in accordance with the procedures established for that purpose by the competent authority, conducted at least one hour of flight instruction for the FI(B) certificate under the supervision and to the satisfaction of an FI(B) who is qualified in accordance with this subparagraph and nominated by the head of training of the ATO or the DTO.

- (b) The privileges listed in paragraph (a) shall include the privileges to conduct flight instruction for:
  - (1) the issue of the relevant licence, privileges, ratings or certificate; and
  - (2) the revalidation, renewal or compliance with the relevant recency requirements of this Annex, as applicable.

## BFCL.320 FI(B) - Prerequisites and requirements

Applicants for an FI(B) certificate shall:

- (a) be at least 18 years of age;
- (b) comply with the requirements of subparagraphs (a)(1)(i) and (a)(2) of point BFCL.300;
- (c) have completed 75 hours of balloon flight time as PIC;
- (d) have completed an instructor training course in accordance with point BFCL.330 at an ATO or a DTO; and
- (e) have passed an assessment of competence in accordance with point BFCL.345.

# BFCL.325 FI(B) competencies and assessment

Applicants for an FI(B) certificate shall be trained to achieve the following competencies:

- (a) prepare resources;
- (b) create a climate conducive to learning;
- (c) present knowledge;
- (d) integrate threat and error management (TEM) and crew resource management (CRM);
- (e) manage time to achieve training objectives;
- (f) facilitate learning;
- (g) assess trainee performance;
- (h) monitor and review progress;
- (i) evaluate training sessions; and
- (j) report outcome.

# BFCL.330 FI(B) - Training course

- (a) Applicants for an FI(B) certificate shall first pass a specific pre-entry assessment at an ATO or a DTO within the 12 months preceding the start of the training course, to assess his or her ability to take the course.
- (b) The FI(B) training course shall include at least:
  - (1) the elements specified in point BFCL.325;
  - (2) 25 hours of teaching and learning;
  - (3) 12 hours of theoretical knowledge instruction, including progress tests; and
  - (4) three hours of flight instruction, including three take-offs and landings.
- (c) Applicants who already hold an instructor certificate in accordance with Annex III (Part-SFCL) to Implementing Regulation (EU) 2018/1976 or with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 shall be fully credited towards the requirement in paragraph (b)(2).

# BFCL.345 FI(B) – Assessment of competence

- (a) Applicants for the issue of an FI(B) certificate shall pass an assessment of competence on a balloon to demonstrate to an examiner qualified in accordance with point BFCL.415(c) the ability to instruct a student pilot to the level required for the issue of a BPL.
- (b) The assessment shall include:
  - the demonstration of the competencies described in point BFCL.325 during pre-flight, post-flight and theoretical knowledge instruction;

- (2) oral theoretical examinations on the ground, pre-flight and post-flight briefings, and in-flight demonstrations in the appropriate balloon class;
- (3) exercises adequate to evaluate the instructor's competencies.

# BFCL.360 FI(B) certificate – Recency requirements

- (a) An FI(B) certificate holder shall only exercise the privileges of his or her certificate if he or she has completed:
  - (1) within the last three years before the planned exercise of those privileges:
    - (i) instructor refresher training at an ATO, a DTO, or a competent authority during which the holder shall receive theoretical knowledge instruction for refreshing and updating the knowledge relevant for balloon instructors;
    - (ii) at least 6 hours of flight instruction in balloons as FI(B); and
  - (2) within the last nine years and in accordance with the procedures established for that purpose by the competent authority, one instruction flight on a balloon as FI(B) under the supervision and to the satisfaction of an FI(B) who is qualified in accordance with point BFCL.315(a)(4) and nominated by the head of training of an ATO or a DTO.
- (b) The hours flown as an FE(B) during skill tests, proficiency checks or assessments of competence shall be fully credited towards the requirement in paragraph (a)(1)(ii).
- (c) If an FI(B) certificate holder has failed to complete the instruction flight under supervision to the satisfaction of the FI(B) in accordance with paragraph (a)(2), he or she shall not exercise the privileges of the FI(B) certificate until he or she has successfully completed an assessment of competence in accordance with point BFCL.345.
- (d) To resume the exercise of the privileges of the FI(B) certificate, an FI(B) certificate holder who does not comply with all the requirements of paragraph (a) shall comply with the requirement of paragraph (a)(1)(i) and of point BFCL.345.

## SUBPART FE

# FLIGHT EXAMINERS

# Section 1

# **General requirements**

#### **BFCL.400 Balloon flight examiner certificates**

(a) General

An examiner shall only carry out skill tests, proficiency checks or assessments of competence in accordance with this Annex if he or she:

- (1) holds:
  - a BPL including privileges, ratings and certificates for which he or she is authorised to conduct skill tests, proficiency checks or assessments of competence, and the privileges to instruct for them;
  - (ii) an FE(B) certificate including privileges appropriate to the skill test, proficiency check or assessment of competence conducted, issued in accordance with this Subpart;
- (2) is entitled to act as PIC in a balloon during the skill test, proficiency check or assessment of competence.
- (b) Examinations conducted outside the territory of the Member States
  - (1) By way of derogation from paragraph (a)(1), in the case of skill tests and proficiency checks performed outside the territory for which Member States are responsible under the Chicago Convention, the competent authority shall issue an examiner certificate to an applicant who holds a balloon pilot licence that is compliant with Annex 1 to the Chicago Convention, provided that the applicant:
    - (i) holds at least a licence including, where relevant, privileges, ratings, or certificates equivalent to those for which he or she is authorised to conduct skill tests or proficiency checks;

- (ii) complies with the requirements established in this Subpart for the issue of the relevant examiner certificate;
- (iii) demonstrates to the competent authority an adequate level of knowledge of European aviation safety rules to be able to exercise examiner privileges in accordance with this Annex.
- (2) The certificate referred to in subparagraph (1) shall be limited to performing skill tests and proficiency checks:
  - (i) outside the territory for which Member States are responsible under the Chicago Convention; and
  - (ii) to a pilot who has sufficient knowledge of the language in which the test/check is provided.

# BFCL.405 Limitation of privileges in case of vested interests

A balloon examiner shall not conduct:

- (a) a skill test or assessment of competence of an applicant for the issue of a licence, rating or certificate to whom he or she has provided more than 50 % of the required flight instruction for the licence, rating or certificate for which the skill test or assessment of competence is taken; or
- (b) a skill test, proficiency check or assessment of competence whenever he or she feels that his or her objectivity may be affected.

# BFCL.410 Conduct of skill tests, proficiency checks and assessments of competence

- (a) When conducting skill tests, proficiency checks and assessments of competence, a balloon examiner shall do all of the following:
  - (1) ensure that communication with the applicant can be established without language barriers;
  - (2) verify that the applicant complies with all the qualification, training and experience requirements of this Annex for the issue, revalidation or renewal of the licence, privileges, rating or certificate for which the skill test, proficiency check or assessment of competence is taken; and
  - (3) make the applicant aware of the consequences of providing incomplete, inaccurate or false information related to his or her training and flight experience.
- (b) After completion of the skill test, proficiency check or assessment of competence, the balloon examiner shall:
  - (1) inform the applicant of the results of the skill test, proficiency check or assessment of competence;
  - (2) in the event of a pass in an assessment of competence for the revalidation or renewal, endorse the new expiry date on the applicant's licence or certificate, if specifically authorised for that purpose by the competent authority that is responsible for the applicant's licence;
  - (3) provide the applicant with a signed report of the skill test, proficiency check or assessment of competence and submit without undue delay copies of the report to the competent authority that is responsible for the applicant's licence, and to the competent authority that issued the examiner certificate. The report shall include:
    - (i) a declaration that the balloon examiner has received information from the applicant regarding his or her experience and instruction, and found that experience and instruction comply with the applicable requirements of this Annex;
    - (ii) confirmation that all the required manoeuvres and exercises have been completed, as well as information on the verbal theoretical knowledge examination, when applicable. If an item has been failed, the examiner shall record the reasons for this assessment;
    - (iii) the results of the skill test, proficiency check or assessment of competence;
    - (iv) a declaration that the balloon examiner has reviewed and applied the national procedures and requirements of the applicant's competent authority if the competent authority that is responsible for the applicant's licence is not the one that issued the examiner's certificate;
    - (v) a copy of the balloon examiner certificate containing the scope of his or her privileges as balloon examiner in the case of skill tests, proficiency checks or assessments of competence of an applicant whose competent authority is not the one that issued the examiner's certificate.

- (c) The balloon examiner shall maintain the records for five years with details of all skill tests, proficiency checks and assessments of competence performed and their results.
- (d) Upon request by the competent authority that is responsible for the balloon examiner certificate, or the competent authority that is responsible for the applicant's licence, the balloon examiner shall submit all records and reports, and any other information, as required, for oversight activities.

# Section 2

# Flight examiner certificate for balloons - FE(B)

#### BFCL.415 FE(B) certificate - Privileges and conditions

Subject to compliance of the applicant with point BFCL.420 and with the following conditions, an FE(B) certificate shall be issued upon application with privileges to conduct:

- (a) skill tests and proficiency checks for the BPL and skill tests for the extension of the privileges to another balloon class, provided that the applicant has completed 250 hours of flight time as pilot on balloons, including 50 hours of flight instruction covering the full syllabus of a BPL training course;
- (b) skill tests and proficiency checks for the commercial operation rating as specified in point BFCL.215, provided that the applicant complies with the experience requirements set out in paragraph (a) and has received specific training during an examiner standardisation course in accordance with point BFCL.430;
- (c) assessments of competence for the issue of an FI(B) certificate, provided that the applicant has:
  - (1) completed 350 hours of flight time as pilot on balloons, including 5 hours of instruction to an applicant for the FI
     (B) certificate;
  - (2) received specific training during an examiner standardisation course in accordance with point BFCL.430.

# BFCL.420 FE(B) certificate - Prerequisites and requirements

Applicants for an FE(B) certificate shall:

- (a) comply with the requirements of subparagraphs (a)(1)(i) and (2) of point BFCL.400;
- (b) have completed the FE(B) standardisation course in accordance with point BFCL.430;
- (c) have completed an assessment of competence in accordance with point BFCL.445;
- (d) demonstrate relevant background related to the privileges of the FE(B) certificate; and
- (e) demonstrate that he or she has not been subject to any sanctions, including the suspension, limitation or revocation of any of his or her licences, ratings or certificates issued in accordance with this Annex, with Annex I (Part-FCL) to Regulation (EU) No 1178/2011, or with Annex III (Part-SFCL) to Implementing Regulation (EU) 2018/1976, for noncompliance with Regulation (EU) 2018/1139 and its delegated and implementing acts during the last three years.

#### BFCL.430 FE(B) certificate – Standardisation course

- (a) Applicants for an FE(B) certificate shall take a standardisation course which is provided either by the competent authority or by an ATO or a DTO and approved by that competent authority.
- (b) The standardisation course shall be tailored to the balloon flight examiner privileges sought and shall consist of theoretical and practical instruction, including, at least:
  - (1) the conduct of at least one skill test, proficiency check or assessment of competence for the BPL or associated ratings or certificates;
  - (2) instruction on the applicable requirements of this Annex and the applicable air operations requirements, the conduct of skill tests, proficiency checks and assessments of competence, and their documentation and reporting;
  - (3) a briefing on the following:
    - (i) national administrative procedures;
    - (ii) requirements for the protection of personal data;

- (iii) examiner's liability;
- (iv) examiner's accident insurance;
- (v) national fees; and
- (vi) information on how to access the information contained in points (i) to (v) when conducting skill tests, proficiency checks or assessments of competence of an applicant whose competent authority is not the one that issued the examiner certificate.
- (c) An FE(B) certificate holder shall not conduct skill tests, proficiency checks or assessments of competence of an applicant whose competent authority is not the one that issued the examiner certificate, unless he or she has reviewed the latest available information containing the relevant national procedures of the applicant's competent authority.

# BFCL.445 FE(B) certificate - Assessment of competence

An applicant for the initial issue of an FE(B) certificate shall demonstrate his or her competences as an FE(B) to an inspector from the competent authority or to a senior examiner specifically authorised to do so by the competent authority that is responsible for the FE(B) certificate. During the assessment of competence, the applicant shall conduct a skill test, proficiency check or assessment of competence, including briefing, conduct of the skill test, proficiency check or assessment of the person to whom the test, check or assessment is given, debriefing and recording documentation.

# BFCL.460 FE(B) certificate - Validity, revalidation and renewal

- (a) An FE(B) certificate shall be valid for five years.
- (b) An FE(B) certificate shall be revalidated if its holder has:
  - (1) during the validity period of the FE(B) certificate, completed an examiner refresher course which is provided either by the competent authority or by an ATO or a DTO and approved by that competent authority, during which the holder shall receive theoretical knowledge instruction for refreshing and updating the knowledge relevant for balloon examiners; and
  - (2) within the last 24 months preceding the end of the validity period of the certificate, conducted one skill test, proficiency check or assessment of competence under the supervision and to the satisfaction of an inspector from the competent authority or an examiner specifically authorised to do so by the competent authority that is responsible for the FE(B) certificate.
- (c) An FE(B) certificate holder who also holds one or more examiner certificates for other aircraft categories in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 or with Annex III (Part-SFCL) to Implementing Regulation (EU) 2018/1976 may achieve combined revalidation of all examiner certificates held, in agreement with the competent authority.
- (d) If an FE(B) certificate has expired, its holder shall comply with the requirements of paragraph (b)(1) and of point BFCL.445 before he or she can resume the exercise of the privileges of the FE(B) certificate.
- (e) An FE(B) certificate shall only be revalidated or renewed if the applicant demonstrates continued compliance with the requirements of point BFCL.410 as well as with the requirements of point BFCL.420(d) and (e).'

# COMMISSION IMPLEMENTING REGULATION (EU) 2020/358

## of 4 March 2020

# amending Implementing Regulation (EU) 2018/1976 as regards sailplane pilot licences

(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 (<sup>1</sup>), and in particular Articles 23, 27 and 31 thereof,

#### Whereas:

- The Commission is to adopt the necessary implementing rules for establishing the requirements for sailplane pilot licences in accordance with Regulation (EU) 2018/1139, where such aircraft meet the conditions specified in points (b)(i) and (ii) of Article 2(1) of that Regulation.
- (2) In light of the specific nature of flight crew licensing for sailplanes, dedicated licensing requirements laid down in stand-alone regulations are necessary. Those requirements should be based on the general rules for flight crew licensing that are laid down in Commission Regulation (EU) No 1178/2011 (<sup>2</sup>). However, they should be restructured and simplified, in order to ensure that they are proportionate and founded on a risk-based approach, whilst ensuring that sailplane pilots are and continue to be competent to carry out their activities and discharge their responsibilities. Corresponding editorial update should also be made to the sailplane operations rules to take account of the shift of licensing rules from Regulation (EU) No 1178/2011 to Commission Implementing Regulation (EU) 2018/1976 (<sup>3</sup>).
- (3) Pursuant to Article 12(2a)(3) of Regulation (EU) No 1178/2011, Member States may continue to apply national licensing rules that provide access to basic pilot privileges until 8 April 2020. Some Member States have reported to the Commission and the European Union Aviation Safety Agency ('EASA') that, in that context, continuation of those national licencing rules, whereby student pilots are allowed to exercise limited privileges without supervision and obtain basic privileges on a step-by-step basis, supports the promotion of aerial sports and recreational activities due to easy and more affordable access to flying. Promoting and enabling such easier access to general aviation is in line with objectives of EASA's General Aviation Road Map that aims to create a more proportional, flexible and proactive regulatory system (\*). For those reasons, Member States should be given the discretion to continue with those national licensing rules in accordance with the principles introduced in Commission Implementing Regulation (EU) 2019/430 (<sup>5</sup>), for the purpose of issuing sailplane pilot licences ('SPL'). However, Member States should also monitor the use of such authorisations in order to maintain an acceptable level of aviation safety.

<sup>(&</sup>lt;sup>1</sup>) OJ L 212, 22.8.2018, p. 1.

<sup>(2)</sup> Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p. 1).

<sup>(&</sup>lt;sup>3</sup>) Commission Implementing Regulation (EU) 2018/1976 of 14 December 2018 laying down detailed rules for the operation of sailplanes pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council (OJ L 326, 20.12.2018, p. 64).

<sup>(\*)</sup> https://www.easa.europa.eu/easa-and-you/general-aviation/general-aviation-road-map

<sup>&</sup>lt;sup>(5)</sup> Commission Implementing Regulation (EU) 2019/430 of 18 March 2019 amending Regulation (EU) No 1178/2011 as regards the exercise of limited privileges without supervision before the issuance of a light aircraft pilot licence (OJ L 75, 19.3.2019, p. 66).

- (4) In order to ensure a smooth transition, any certificates, authorisations and approvals issued to sailplane pilots in accordance with Regulation (EU) No 1178/2011 prior to the date of application of this Regulation should continue to be valid. National sailplane pilot licences issued prior to the date of application of this Regulation should be converted into licences issued in accordance with this Regulation, through conversion reports established by the competent authorities of Member States in consultation with the EASA.
- (5) Sailplane pilot trainings that commenced in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 prior to the date of application of this Regulation should be fully credited because they provide equal or even broader scope of training requirements than those introduced by this Regulation. Training that commenced prior to the date of application of this Regulation in accordance with Annex 1 to the Chicago Convention should be credited on the basis of credit reports established by the Member States.
- (6) Existing training organisations should be given the appropriate time to adapt their training programmes, where necessary, in the context of the simplified training requirements.
- (7) The measures provided for in this Regulation are based on Opinion No 01/2019 (°) of the EASA in accordance with points (b) and (c) of Article 75(2) and with Article 76(1) of Regulation (EU) 2018/1139.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 127 of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

#### Article 1

Implementing Regulation (EU) 2018/1976 is amended as follows:

(1) the title is replaced by the following:

'Commission Implementing Regulation (EU) 2018/1976 of 14 December 2018 laying down detailed rules for the operation of sailplanes as well as for the flight crew licensing for sailplanes pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council';

(2) in Article 1, paragraph 1 is replaced by the following:

1. This Regulation lays down detailed rules for air operations with sailplanes as well as for issuing and maintaining pilot licences and associated ratings, privileges and certificates for sailplanes, where such aircraft meet the conditions laid down in points (b)(i) and (ii) of Article 2(1) of Regulation (EU) 2018/1139.';

- (3) Article 2 is amended as follows:
  - (a) the introductory sentence is replaced by the following:

'For the purposes of this Regulation, the following definitions and, unless terms are defined otherwise in this Article, the definitions of Article 2 of Regulation (EU) No 1178/2011 apply:';

- (b) point (10) is replaced by the following:
  - (10) "dry lease agreement" means an agreement between undertakings pursuant to which the sailplane is operated under the responsibility of the lessee;";
- (c) the following points (11) to (13) are added:
  - (11) "national licence" means a pilot licence issued by a Member State in accordance with national legislation before the date of application of Annex III (Part-SFCL) to this Regulation or of Annex I (Part-FCL) to Regulation (EU) No 1178/2011;

<sup>(°)</sup> Easier access for GA pilots to IFR flying & Revision of the balloon and sailplane licensing requirements, (Opinion No 01/2019 (A) & (B), 19.02.2019), available at: https://www.easa.europa.eu/document-library/opinions

- (12) "Part-SFCL licence" means a flight crew licence which complies with the requirements of Annex III (Part-SFCL) to this Regulation;
- (13) "conversion report" means a report on the basis of which a licence may be converted into a Part-SFCL licence;';
- (4) the following Articles 3a to 3d are inserted after Article 3:

'Article 3a

## Pilot licences and medical certification

1. Without prejudice to Commission Delegated Regulation (EU) (\*), pilots of aircraft referred to in Article 1(1) of this Regulation shall comply with the technical requirements and administrative procedures laid down in Annex III (Part-SFCL) to this Regulation and in Annex IV (Part-MED) to Regulation (EU) No 1178/2011.

2. As an exception to the privileges of the holders of licences as defined in Annex III (Part-SFCL) to this Regulation, holders of such licences may carry out flights referred to in points (a) to (d) of Article 3(2) without complying with point SFCL.115(a)(3) of Annex III (Part-SFCL) to this Regulation.

3. A Member State may authorise student pilots who follow a sailplane pilot licence ('SPL') training course to exercise limited privileges without supervision before they meet all the requirements that are necessary for the issue of an SPL in accordance with Annex III (Part-SFCL) to this Regulation, subject to all of the following conditions:

- (a) the scope of the privileges granted shall be based on a safety risk assessment carried out by the Member State, taking into account the extent of training necessary for the intended level of pilot competence to be achieved;
- (b) the privileges shall be limited to the following:
  - (i) the whole or part of the national territory of the authorising Member State; and
  - (ii) sailplanes that are registered in the authorising Member State;
- (c) the holder of an authorisation who applies for the issue of an SPL shall receive credits for training conducted on the basis of a recommendation from an approved training organisation ('ATO') or a declared training organisation ('DTO');
- (d) the Member State shall submit reports and safety risk assessments to the Commission and the European Union Aviation Safety Agency ('EASA') every 3 years;
- (e) the Member State shall monitor the use of authorisations issued under this paragraph to ensure an acceptable level of aviation safety and take appropriate action in case of identifying an increased safety risk or any safety concerns.

#### Article 3b

# Existing pilot licences and national medical certificates

1. Part-FCL licences for sailplanes and associated privileges, ratings and certificates issued by a Member State before the date of application of this Regulation shall be deemed to have been issued in accordance with this Regulation. Member States shall replace those licences with licences that comply with the format laid down in Annex VI (Part-ARA) to Regulation (EU) No 1178/2011 when they reissue licences for administrative reasons or upon a request of licence holders.

2. When a Member State reissues licences and associated privileges, ratings and certificates in accordance with paragraph 1, the Member State shall, as applicable:

- (a) transfer all privileges endorsed so far in Part-FCL licences to the new licence format;
- (b) convert aerobatic ratings issued in accordance with point FCL.800 of Annex I (Part-FCL) to Regulation (EU) No 1178/2011 into advanced aerobatic privileges in accordance with point SFCL.200(c) of Annex III (Part-SFCL) to this Regulation;
- (c) endorse the expiry date of a flight instructor certificate associated with a Part-FCL licence into the pilot's logbook or issue an equivalent document. After that expiry date, pilots shall exercise instructor privileges only when they comply with point SFCL.360 of Annex III (Part-SFCL) to this Regulation.

3. Holders of national licences for sailplanes issued by a Member State before the date of application of Annex III (Part-SFCL) to this Regulation shall be allowed to continue to exercise the privileges of their licences until 8 April 2021. By that date, Member States shall convert those licences into Part-SFCL licences and associated ratings, privileges and certificates in accordance with the elements laid down in a conversion report that complies with the requirements of Article 4(4) and (5) of Regulation (EU) No 1178/2011.

4. National pilot medical certificates associated with a licence as specified in paragraph 2 of this Article and issued by a Member State before the date of application of Annex III (Part-SFCL) to this Regulation shall remain valid until the date of their next revalidation or until 8 April 2021, whichever is the earliest. The revalidation of such medical certificates shall comply with the requirements of Annex IV (Part-MED) to Regulation (EU) No 1178/2011.

Article 3c

# Credit for training that commenced prior to the date of application of this Regulation

1. In respect of issuing Part-SFCL licences and associated privileges, ratings or certificates in accordance with Annex III (Part-SFCL) to this Regulation, training that commenced prior to the date of application of this Regulation in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 shall be deemed to comply with the requirements of this Regulation.

2. Training that commenced prior to the date of application of this Regulation or of Annex I (Part-FCL) to Regulation (EU) No 1178/2011, in accordance with Annex 1 to the Chicago Convention, shall be credited for the purposes of issuing Part-SFCL licences on the basis of a credit report established by the Member State in consultation with the EASA.

3. The credit report referred to in paragraph 2 shall describe the scope of the training, indicate for which requirements of Part-SFCL credit is given and, if applicable, which requirements applicants need to comply with in order to be issued with a Part-SFCL licence. It shall include copies of all the documents necessary to attest the scope of the training, as well as copies of the national regulations and procedures in accordance with which the training was initiated.

Article 3d

# Training organisations

1. Training organisations for obtaining the pilot licences referred to in Article 1(1) of this Regulation shall comply with the requirements of Article 10a of Regulation (EU) No 1178/2011.

2. Training organisations referred to in paragraph 1 which hold an approval issued in accordance with Annex VII (Part-ORA) to Regulation (EU) No 1178/2011 or have submitted a declaration in accordance with Annex VIII (Part-DTO) to Regulation (EU) No 1178/2011 before the date of application of this Regulation shall adapt their training programmes, where necessary, by 8 April 2021 at the latest.

(\*) Commission Delegated Regulation (EU) of 4 March 2020 (not yet published in the Official Journal).';

- (5) Annex I (Part-DEF) is amended in accordance with Annex I to this Regulation;
- (6) Annex II (Part-SAO) is amended in accordance with Annex II to this Regulation
- (7) Annex III (Part-SFCL) is added as set out in Annex III to this Regulation.

## Article 2

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

It shall apply from 8 April 2020.

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

Done at Brussels, 4 March 2020.

For the Commission The President Ursula VON DER LEYEN

# L 67/62

EN

## ANNEX I

Annex I 'Definitions' (Part-DEF) to Regulation (EU) 2018/1976 is amended as follows:

(1) the introductory sentence is replaced by the following:

'For the purpose of this Regulation, the following definitions and, unless terms are defined otherwise in this Annex, the definitions of Article 2 of Commission Regulation (EU) No 1178/2011 as well as of point FCL.010 of Annex I (Part-FCL) to that Regulation, shall apply:';

- (2) point 13 is replaced by the following:
  - '13. "night" means the period between the end of evening civil twilight and the beginning of morning civil twilight. Civil twilight ends in the evening when the centre of the sun's disc is six degrees below the horizon and begins in the morning when the centre of the sun's disc is six degrees below the horizon;';
- (3) the following points 14 to 19 are added:
  - '14. "skill test" means the demonstration of skill for the purpose of issuing a licence or rating, or extension of a privilege, including oral examinations as may be required;
  - 15. "assessment of competence" means the demonstration of skill, knowledge and attitude for the initial issue, revalidation or renewal of an instructor or examiner certificate;
  - 16. "flight time" means:
    - (a) for self-launch sailplanes and touring motor gliders, the total time from the moment an aircraft first moves for the purpose of taking off until the moment it finally comes to rest at the end of the flight;
    - (b) for sailplanes, the total time from the moment the sailplane commences the ground run in the process of taking off until the moment the sailplane finally comes to a rest at the end of flight;
  - 17. "proficiency check" means the demonstration of skill for the purpose of complying with the recency requirements as established in this Regulation, and including oral examinations as may be required;
  - 18. "solo flight" means a flight during which a student pilot is the sole occupant of an aircraft;
  - 19. "cross-country flight" means a flight outside the line of sight or distance defined by the competent authority from the field of departure using standard navigation procedures.'

# ANNEX II

Annex II (Part-SAO) to Regulation (EU) 2018/1976 is amended as follows:

(1) Point SAO.GEN.125 'Designation of the pilot-in-command' is replaced by the following:

# 'Point SAO.GEN.125 Designation of the pilot-in-command

The operator shall designate a pilot-in-command who is qualified to act as pilot-in-command in accordance with Annex III to this Regulation.'.

## ANNEX III

The following Annex III to Regulation (EU) 2018/1976 is added after Annex II:

# 'ANNEX III

# **REQUIREMENTS FOR SAILPLANE FLIGHT CREW LICENSING**

## [PART-SFCL]

## SUBPART GEN

# GENERAL REQUIREMENTS

# SFCL.001 Scope

This Annex establishes the requirements for the issue of a sailplane pilot licence ('SPL') and associated privileges, ratings and certificates, and the conditions for their validity and use.

#### SFCL.005 Competent authority

For the purpose of this Annex, the competent authority shall be an authority designated by the Member State to which a person applies for the issue of an SPL or associated privileges, ratings or certificates.

# SFCL.015 Application for and issue, revalidation and renewal of an SPL as well as associated privileges, ratings and certificates

- (a) The following shall be submitted to the competent authority in a form and manner established by that competent authority:
  - (1) an application for:
    - (i) the issue of an SPL and associated ratings;
    - (ii) the extension of the privileges of an SPL, except for the privileges specified in points SFCL.115(a)(2) and (a)(3), SFCL.155, SFCL.200 and SFCL.215;
    - (iii) the issue of a sailplane flight instructor ('FI(S)') certificate;
    - (iv) the issue, revalidation and renewal of a sailplane flight examiner ('FE(S)') certificate;
    - (v) any amendments to the SPL and associated privileges, ratings and certificates, except for the privileges referred to in point (ii); and
  - (2) if mandated by the competent authority, a copy of the relevant logbook entries as specified in points SFCL.115(d), SFCL.155(b), SFCL.200(f) and SFCL.215(d).
- (b) An application as specified in paragraph (a) shall be accompanied by evidence that the applicant complies with the relevant requirements established in this Annex and in Annex IV (Part-MED) to Regulation (EU) No 1178/2011.
- (c) Any limitation or extension of the privileges granted by a licence, rating or certificate shall be endorsed on the licence or certificate by the competent authority, except for obtaining the privileges as specified in paragraph (a)(1)(ii).
- (d) A person shall not hold at any time more than one SPL issued in accordance with this Annex.
- (e) A licence holder shall submit applications as specified in paragraph (a) to the competent authority designated by the Member State in which any of his or her licences was issued in accordance with this Annex (Part-SFCL), or Annex I (Part-FCL) to Regulation (EU) No 1178/2011 or Annex III (Part-BFCL) to Regulation (EU) 2018/395, as applicable.
- (f) An SPL holder may apply for a change of competent authority to the competent authority designated by another Member State but in such case the new competent authority shall be the same for all the licences held.

(g) Applicants shall apply for the issue of an SPL and associated ratings, privileges or certificates not later than six months after having successfully completed the skill test or assessment of competence.

## SFCL.030 Practical skill test

Applicants for a skill test shall be recommended for the skill test by the ATO or the DTO that is responsible for the training undertaken by the applicants, once the training is completed. The training records shall be made available to the examiner by the ATO or DTO.

# SFCL.035 Crediting of flight time

Applicants for an SPL or an associated privilege, rating or certificate shall be fully credited with all solo, dual instruction or PIC flight time on sailplanes towards the requirement of a total flight time for the licence, privilege, rating or certificate.

#### SFCL.045 Obligation to carry and present documents

- (a) When exercising the privileges of SPL licence, SPL holders shall carry all of the following:
  - (1) a valid SPL;
  - (2) a valid medical certificate;
  - (3) a personal identification document containing his or her photo;
  - (4) sufficient logbook data to demonstrate compliance with the requirements of this Annex.
- (b) Student pilots shall carry on all solo cross-country flights:
  - (1) the documents as specified in paragraphs (a)(2) and (a)(3);
  - (2) evidence of the authorisation required by point SFCL.125(a).
- (c) SPL holders or student pilots shall without undue delay present the documents as specified in paragraph (a) for inspection upon request by an authorised representative of the competent authority.
- (d) By way of derogation from paragraphs (a) and (b), the documents specified therein may be retained at the aerodrome or operating site for flights that remain:
  - (1) within the sight of the aerodrome or operating site; or
  - (2) within a distance from the aerodrome or operating site determined by the competent authority.

# SFCL.050 Recording of flight time

SPL holders and student pilots shall keep a reliable record of the details of all flights flown in a form and manner established by the competent authority.

# SFCL.065 Curtailment of privileges of SPL holders aged 70 years or older in commercial passenger sailplane operations

SPL holders who have attained the age of 70 years shall not act as pilots of sailplanes engaged in commercial passenger sailplane operations.

# SFCL.070 Limitation, suspension and revocation of licences, privileges, ratings and certificates

(a) An SPL as well as associated privileges, ratings and certificates issued in accordance with this Annex may be limited, suspended or revoked by the competent authority in accordance with the conditions and procedures laid down in Annex VI (Part-ARA) to Regulation (EU) No 1178/2011 if an SPL holder does not comply with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139 or with the requirements of this Annex as well as of Annex II (Part-SAO) to this Regulation or with Annex IV (Part-MED) to Regulation (EU) No 1178/2011.

(b) SPL holders shall immediately return the licence or certificate to the competent authority if their licence, privilege, rating or certificate has been limited, suspended or revoked.

#### SUBPART SPL

#### SAILPLANE PILOT LICENCE ('SPL')

# SFCL.115 SPL - Privileges and conditions

- (a) Subject to compliance with point SFCL.150, the privileges of SPL holders are to act as PIC in sailplanes:
  - (1) without remuneration in non-commercial operations;
  - (2) including the carriage of passengers only if they:
    - (i) comply with point SFCL.160(e); and
    - (ii) either:
      - (A) have completed, after the issue of the SPL, at least 10 hours of flight time or 30 launches or take-offs and landings as PIC on sailplanes and, additionally, one training flight during which holders shall demonstrate to an FI(S) the competence required for the carriage of passengers; or
      - (B) hold an FI(S) certificate in accordance with Subpart FI;
  - (3) in operations other than those specified in paragraph (1), only if they have:
    - (i) attained the age of 18 years;
    - (ii) completed, after the issue of the licence, 75 hours of flight time or 200 launches or take-offs and landings as PIC on sailplanes.
- (b) By way of derogation from paragraph (a), SPL holders who have instructor or examiner privileges may receive remuneration for:
  - (1) the provision of flight instruction for the SPL;
  - (2) the conduct of skill tests and proficiency checks for the SPL;
  - (3) the training, testing and checking for the privileges, ratings and certificates attached to an SPL.
- (c) SPL holders shall exercise SPL privileges only if they comply with the applicable recency requirements and only if their medical certificate, appropriate to the privileges exercised, is valid.
- (d) The completion of the training flight as specified in paragraph (a)(2)(ii)(A) shall be entered in the logbook of the pilot and signed by the instructor who is responsible for the training flight.

# SFCL.120 SPL – Minimum age

Applicants for an SPL shall be at least 16 years old.

# SFCL.125 SPL – Student pilot

- (a) Student pilots shall not fly solo unless authorised to do so and supervised by an FI(S).
- (b) Student pilot shall be at least 14 years of age to be allowed on solo flights.

# SFCL.130 SPL - Training course and experience requirements

- (a) Applicants for an SPL shall complete a training course at an ATO or a DTO. The course shall be tailored to the privileges sought and shall include:
  - (1) theoretical knowledge as specified in point SFCL.135;

- (2) at least 15 hours of flight instruction in sailplanes, including at least:
  - (i) 10 hours of dual flight instruction which shall include the dual flight instruction as specified in paragraphs (iv)
     (A) or (v)(A), as applicable;
  - (ii) two hours of supervised solo flight time;
  - (iii) 45 launches or take-offs and landings;
  - (iv) if privileges for sailplanes, excluding TMGs, are sought, at least seven hours of flight instruction in sailplanes, excluding TMGs, and including at least:
    - (A) three hours of dual flight instruction;
    - (B) either:
      - (a) one solo cross-country flight of at least 50 km (27 NM); or
      - (b) one dual cross-country flight of at least 100 km (55 NM) which, by way of derogation from paragraph (2)(iv), may be completed in a TMG;
  - (v) if privileges for TMGs are sought, at least six hours of flight instruction in TMGs, including at least:
    - (A) four hours of dual flight instruction;
    - (B) one solo cross-country flight of at least 150 km (80 NM) in a TMG, during which one full-stop landing at an aerodrome different from the aerodrome of departure shall be performed.
- (b) Applicants who hold a pilot licence for another category of aircraft, with the exception of balloons licence, shall be credited with 10 % of total flight time as PIC on such aircraft and up to a maximum of seven hours. The amount of credit given shall in any case:
  - (1) not include the requirements of paragraphs (a)(2)(ii), (a)(2)(iv)(B) and (a)(2)(v)(B); and
  - (2) with regard to paragraph (a)(2)(iii), not exceed 10 launches or take-offs and landings.

## SFCL.135 SPL – Theoretical knowledge examination

(a) Theoretical knowledge

Applicants for an SPL shall demonstrate a level of theoretical knowledge that is appropriate to the privileges sought through examinations on the following:

- (1) common subjects:
  - (i) air law;
  - (ii) human performance;
  - (iii) meteorology;
  - (iv) communications;
- (2) specific subjects concerning sailplanes:
  - (i) principles of flight;
  - (ii) operational procedures;
  - (iii) flight performance and planning;
  - (iv) aircraft general knowledge related to sailplanes;
  - (v) navigation.

- (b) Responsibilities of the applicant
  - (1) The applicant shall take the entire set of theoretical knowledge examinations for the SPL under the responsibility of the same Member State's competent authority.
  - (2) The applicant shall take the theoretical knowledge examination only if recommended by the ATO or the DTO that is responsible for his or her training and once he or she has completed the appropriate elements of the training course of theoretical knowledge instruction to a satisfactory standard.
  - (3) The recommendation by the ATO or the DTO shall be valid for 12 months. If the applicant has failed to take at least one theoretical knowledge examination paper within this validity period, the need for further training shall be determined by the ATO or the DTO, based on the needs of the applicant.
- (c) Pass standards
  - (1) A pass in a theoretical knowledge examination shall be awarded to the applicant when achieving at least 75 % of the marks allocated to that paper. No penalty marking shall be applied.
  - (2) Unless otherwise specified in this Annex, an applicant is considered to have successfully completed the required theoretical knowledge examination for the SPL if he or she has passed all the required theoretical knowledge examination papers within a period of 18 months counted from the end of the calendar month when the applicant first attempted to take the examination.
  - (3) If an applicant has failed to pass one of the theoretical knowledge examination papers within four attempts or has failed to pass all papers within the period mentioned in paragraph (2), he or she shall retake the complete set of theoretical knowledge examination papers.
  - (4) Before retaking the theoretical knowledge examinations, the applicant shall undertake further training at an ATO or a DTO. The extent and scope of the training needed shall be determined by the ATO or the DTO, based on the needs of the applicant.
- (d) Validity period

The successful completion of the theoretical knowledge examinations shall be valid for a period of 24 months, counted from the day when the applicant successfully completed the theoretical knowledge examination, in accordance with paragraph (c)(2).

# SFCL.140 SPL – Crediting of theoretical knowledge

Applicants for the issue of an SPL shall be credited towards the theoretical knowledge requirements for the common subjects as specified in point SFCL.135(a)(1) if they:

- (a) hold a licence in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 or with Annex III (Part-BFCL) to Regulation (EU) 2018/395; or
- (b) have passed the theoretical knowledge examinations for a licence as specified in paragraph (a), as long as this is done within the validity period specified in point SFCL.135(d).

# SFCL.145 SPL – Practical skill test

- (a) Applicants for an SPL shall demonstrate through the completion of a skill test the ability to perform, as PIC on sailplanes, the relevant procedures and manoeuvres with competency appropriate to the privileges sought.
- (b) Applicants shall complete the skill test in a sailplane, excluding TMGs, or a TMG, depending on the privileges sought and provided that the training course in accordance with point SFCL.130 included the necessary training elements for the relevant aircraft. An applicant who has completed a training course, including the necessary training elements for both sailplanes and TMGs, may complete 2 skill tests, 1 in a sailplane, excluding TMGs, and 1 in a TMG, in order to obtain privileges for both aircraft.
- (c) To take a skill test for the issue of an SPL the applicant shall first pass the required theoretical knowledge examinations.

- (d) Pass standards
  - (1) The skill test shall be divided into different sections, representing all the different phases of a sailplane flight.
  - (2) Failure in any item of a section shall cause the applicant to fail the entire section. If the applicant fails in only one section, he or she shall repeat only that section. Failure in more than one section shall require the applicant to retake the entire test.
  - (3) If the applicant needs to retake the test in accordance with paragraph (2) and fails in any section, including those sections that have been passed at a previous attempt, the applicant shall retake the entire test.
- (e) If the applicant fails to achieve a pass in all sections of the test within two attempts he or she shall receive further practical training.

# SFCL.150 SPL – Sailplane and TMG privileges

- (a) If the skill test as specified in point SFCL.145 has been completed in a sailplane, excluding TMGs, the privileges of an SPL shall be limited to sailplanes, excluding TMGs.
- (b) In the case specified in paragraph (a), the privileges of an SPL shall be extended to TMGs upon application if a pilot has:
  - (1) completed at an ATO or a DTO the training elements specified in point SFCL.130(a)(2)(v);
  - (2) passed a skill test to demonstrate an adequate level of practical skill in a TMG. During this skill test, the applicant shall also demonstrate to the examiner an adequate level of theoretical knowledge for TMGs in the following subjects:
    - (i) principles of flight;
    - (ii) operational procedures;
    - (iii) flight performance and planning;
    - (iv) aircraft general knowledge; and
    - (v) navigation.
- (c) Holders of a licence issued in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 shall receive full credit towards the requirements in paragraph (b) provided that they:
  - (1) hold a class rating for TMGs; or
  - (2) have TMG privileges and comply with the recency requirements in point FCL.140.A of Annex I (Part-FCL) to Regulation (EU) No 1178/2011.
- (d) If the skill test as specified in point SFCL.145 has been completed in a TMG, the privileges of the SPL shall be limited to TMGs.
- (e) In the case specified in paragraph (d), the privileges of the SPL shall be extended to sailplanes upon application if a pilot has:
  - (1) completed at an ATO or a DTO the training elements specified in point SFCL.130(a)(2)(iv) and at least 15 launches and landings in a sailplane, excluding TMGs; and
  - (2) passed a skill test to demonstrate an adequate level of practical skill in a sailplane, excluding TMGs. During this skill test, the pilot shall also demonstrate to the examiner an adequate level of theoretical knowledge for sailplanes, excluding TMGs, in the following subjects:
    - (i) principles of flight;
    - (ii) operational procedures;
    - (iii) flight performance and planning;

- (iv) aircraft general knowledge; and
- (v) navigation.
- (f) The completion of the training as specified in paragraphs (b)(1) and (e)(1) shall be entered in the logbook of the pilot and signed by the head of training of the ATO or the DTO that is responsible for the training.

#### SFCL.155 SPL – Launching methods

- (a) SPL holders shall exercise their privileges only by using those launching methods for which they have completed a specific training either during the training course in accordance with point SFCL.130 or point SFCL.150(e)(1) or during additional training provided by an instructor after the issue of the SPL. This specific training shall consist of the following:
  - in the case of winch launch and car launch, a minimum of 10 launches in dual flight instruction, and five solo launches under supervision;
  - (2) in the case of aerotow or self-launch, a minimum of five launches in dual flight instruction, and five solo launches under supervision. In the case of self-launch, dual flight instruction may be conducted in TMGs;
  - (3) in the case of bungee launch, a minimum of three launches performed in dual flight instruction or solo under supervision; and
  - (4) in case of further launching methods, training as required by the competent authority.
- (b) The completion of the training as specified in paragraph (a) shall be entered in the logbook of the pilot and signed by the head of training of the ATO or the DTO or the instructor that is responsible for the training, as applicable.
- (c) In order to maintain the privileges for each launching method and in accordance with the requirements of paragraphs (a) and (b), SPL holders shall complete a minimum of five launches during the last two years, except for bungee launch, in which case they shall complete only two launches. In the case of self-launch, launches may be done in self-launch or through take-offs in TMGs or a combination of these.
- (d) If SPL holders do not comply with the requirement in paragraph (c), in order to renew their privileges they shall perform the additional number of launches flying dual or solo under the supervision of an instructor.

## SFCL.160 SPL - Recency requirements

(a) Sailplanes, excluding TMGs

SPL holders shall exercise SPL privileges, excluding TMGs, only if in the last 24 months before the planned flight they:

- (1) completed, on sailplanes, at least five hours of flight time as PIC or flying dual or solo under the supervision of an FI(S), including, on sailplanes, excluding TMGs, at least:
  - (i) 15 launches; and
  - (ii) two training flights with an FI(S); or
- (2) passed a proficiency check with an FE(S) on a sailplane, excluding TMGs; the proficiency check shall be based on the skill test for SPL.
- (b) TMGs
  - SPL holders shall exercise their TMG privileges only if in the last 24 months before the planned flight they:
  - (1) completed at least 12 hours of flight time as PIC or flying dual or solo under the supervision of an FI(S), including, on TMGs, at least:
    - (i) six hours flight time;
    - (ii) 12 take-offs and landings; and
    - (iii) a training flight of at least one hour total flight time with an instructor; or

- (2) passed a proficiency check with an examiner; the proficiency check shall be based on the skill test as specified in point SFCL.150(b)(2).
- (c) SPL holders with privileges to fly on TMGs who also hold a licence including the privileges to fly on TMGs in accordance with the provisions of Annex I (Part-FCL) to Regulation (EU) No 1178/2011 shall be exempted from complying with paragraph (b).
- (d) The completion of the dual flights, the flights under supervision and the training flights as specified in paragraphs (a)(1) and (b)(1), as well as the proficiency checks as specified in paragraph (a)(2) and (b)(2) shall be entered in the logbook of the pilot and signed by the responsible FI(S) in the case of paragraphs (a)(1) and (b)(1), and by the responsible FE(S) in the case of paragraphs (a)(2) and (b)(2).
- (e) Carriage of passengers
  - SPL holders shall carry passengers only if in the preceding 90 days they have carried out as PIC, at least:
  - (1) three launches in sailplanes, excluding TMGs, if passengers are to be carried in sailplanes, excluding TMGs; or
  - (2) three take-offs and landings in TMGs, if passengers are to be carried in a TMG. For carrying passengers at night in a TMG, at least one of those take-offs and landings shall be carried out at night.

#### SUBPART ADD

## ADDITIONAL RATINGS AND PRIVILEGES

## SFCL.200 Aerobatic privileges

- (a) SPL holders shall only undertake aerobatic flights in sailplanes with any engine stopped, or, in the case of paragraph (d) and (e), with engine power, if they hold the appropriate aerobatic privileges in accordance with this point.
- (b) Basic aerobatic privileges:
  - (1) entitle its holder to undertake aerobatic flights limited to the following manoeuvres:
    - (i) 45-degree climbing and diving lines performed as aerobatic manoeuvres;
    - (ii) inside loops;
    - (iii) wingover;
    - (iv) lazy eight;
    - (v) spins;
  - (2) are included in the privileges of an SPL after a pilot has completed:
    - (i) after the issue of the SPL, at least 30 hours of flight time or 120 launches as PIC on sailplanes;
    - (ii) a training course at an ATO or a DTO, including:
      - (A) theoretical knowledge instruction appropriate for the privileges sought;
      - (B) aerobatic flight instruction on the manoeuvres specified in paragraph (1).
- (c) Advanced aerobatic privileges:
  - (1) entitle its holder to undertake aerobatic flights not limited to manoeuvres as specified in paragraph (b)(1);
  - (2) are included in the privileges of an SPL after a pilot has:
    - (i) complied with the requirements of paragraph (b)(2)(i);
    - (ii) completed a training course at an ATO or a DTO, including:
      - (A) theoretical knowledge instruction appropriate for the privileges sought;
      - (B) at least five hours or 20 flights of aerobatic flight instruction.

- (d) The basic or advanced aerobatic privileges shall include aerobatic flights in sailplanes with engine power, if a pilot has received a training in aerobatic flight in sailplanes with engine power during a training course in accordance with paragraphs (b)(2)(ii) or (c)(2)(ii), as applicable.
- (e) The privileges of an SPL shall include advanced aerobatic privileges for TMGs flown with engine power if a pilot also has or has had an aerobatic rating in accordance with point FCL.800 of Annex I (Part-FCL) to Regulation (EU) No 1178/2011, including privileges for aerobatic flight on TMGs.
- (f) The completion of the training course as specified in paragraphs (b)(2)(ii) and (c)(2)(ii) and, as applicable, the inclusion of training specified in paragraph (d), shall be entered in the logbook and signed by the head of training of the ATO or the DTO that is responsible for the training.

### SFCL.205 Sailplane towing and banner towing rating

- (a) SPL holders who have privileges to fly TMGs shall tow sailplanes or banners only if they hold an appropriate sailplane towing or banner towing rating in accordance with this point.
- (b) Applicants for a sailplane towing rating shall have completed:
  - (1) at least 30 hours of flight time as PIC and 60 take-offs and landings in TMGs, after obtaining TMG privileges;
  - (2) a training course at an ATO or a DTO, including:
    - (i) theoretical knowledge instruction on sailplane towing operations and procedures;
    - (ii) at least 10 training flights towing a sailplane, including at least 5 dual training flights;
    - (iii) in the case of an SPL holder with privileges restricted to TMG in accordance with point SFCL.150(d), five familiarisation flights in a sailplane which is launched by an aircraft.
- (c) Applicants for a banner towing rating shall have completed:
  - (1) at least 100 hours of flight time and 200 take-offs and landings as PIC on TMGs, after obtaining TMG privileges;
  - (2) a training course at an ATO or a DTO, including:
    - (i) theoretical knowledge instruction on banner towing operations and procedures;
    - (ii) at least 10 instruction flights towing a banner, including at least five dual flights.
- (d) Applicants for a sailplane towing rating or a banner towing rating in accordance with this point who already hold a sailplane towing or banner towing rating in accordance with point FCL.805(b) of Annex I (Part-FCL) to Regulation (EU) No 1178/2011 or who have fulfilled all the requirements for the issue of that rating, as applicable, shall:
  - receive full credit towards the requirements in paragraph (b) or (c) for obtaining the sailplane towing or the banner towing rating, as applicable, if their relevant towing rating as specified in paragraph (d) includes privileges for towing with TMGs; or
  - (2) have completed at least three dual instruction flights covering the full sailplane towing or banner towing training syllabus, as applicable, in TMGs.
- (e) The completion of the training course as specified in paragraphs (b)(2), (c)(2) and (d)(2) shall be entered in the logbook and signed by the head of training of the ATO or the DTO or the instructor who is responsible for the training, as applicable.
- (f) To exercise the privileges of the sailplane towing or banner towing rating, the holder of the rating shall complete a minimum of five tows during the last two years.
- (g) If a holder of the sailplane towing rating does not comply with the requirement in paragraph (f), before resuming the exercise of his or her privileges, he or she shall complete the missing tows with or under the supervision of an instructor.

## SFCL.210 TMG night rating

- (a) SPL holders with privileges to fly TMGs shall only exercise their TMG privileges in VFR conditions at night if they hold a TMG night rating in accordance with this point.
- (b) Applicants for a TMG night rating shall first complete a training course at an ATO or a DTO. The course shall comprise:
  - (1) theoretical knowledge instruction in flying in visual flight rules (VFR) conditions at night;
  - (2) at least five hours of flight time in TMGs at night, including at least three hours of dual instruction, including at least:
    - (i) One hour of cross-country navigation with at least 1 dual cross-country flight of at least 50 km (27 NM);
    - (ii) Five solo take-offs; and
    - (iii) Five solo full-stop landings.
- (c) To complete the training at night, an SPL holder shall first complete the basic instrument flight training necessary for the issue of a private pilot licence (PPL) in accordance with the provisions of Annex I (Part-FCL) to Regulation (EU) No 1178/2011.
- (d) Applicants for a TMG night rating in accordance with this point shall receive full credit towards the requirements of paragraphs (b) and (c) if they hold a night rating in accordance with point FCL.810 of Annex I (Part-FCL) to Regulation (EU) No 1178/2011 or if they have fulfilled all the requirements for the issue of that rating.

## SFCL.215 Sailplane cloud flying privileges

- (a) SPL holders shall operate a sailplane within cloud only if:
  - (1) any engine is stopped; and
  - (2) they have sailplane cloud flying privileges in accordance with this point.
- (b) The privileges of an SPL shall include sailplane cloud flying privileges if a pilot has completed at least:
  - (1) 30 hours as PIC in sailplanes after the issue of the licence;
  - (2) a training course at an ATO or a DTO, including:
    - (i) theoretical knowledge instruction;
    - (ii) at least two hours of dual flight instruction in sailplanes with any engine stopped, controlling the aircraft solely by reference to instruments. However, a maximum of 50 % of the dual flight instruction may be completed in TMGs flown with engine power, provided that these training flights are conducted in VMC.
- (c) In order to obtain sailplane cloud flying privileges, an SPL holder who also holds a basic instrument rating (BIR) or an IR(A) in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 or who has fulfilled all the requirements for the issue of one of these ratings, shall:
  - (1) be credited towards the requirement of paragraph (b)(2)(i);
  - (2) by way of derogation from paragraph (b)(2)(ii), complete at least one hour of dual flight instruction in a sailplane, controlling it solely by reference to instruments.
- (d) The completion of the training course as specified in paragraphs (b)(2) or (c)(2), as applicable, shall be entered in the logbook and signed by the head of training of the ATO or the DTO that is responsible for the training.
- (e) SPL holders shall exercise their sailplane cloud flying privileges only if in the last two years before the planned cloud flight they have completed at least one hour of flight time, or five flights, as PIC exercising cloud flying privileges in sailplanes.

- (f) If SPL holders with sailplane cloud flying privileges do not comply with the requirements in paragraph (e) and they wish to resume the exercise of their sailplane cloud flying privileges they shall:
  - (1) pass a proficiency check with an FE(S); or
  - (2) perform the additional flight time or flights required in paragraph (e) with an FI(S).
- (g) SPL holders with sailplane cloud flying privileges who also hold a BIR or an IR(A) in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 shall be fully credited towards the requirements of paragraph (e).

#### SUBPART FI

#### FLIGHT INSTRUCTORS

#### Section 1

#### **General requirements**

## SFCL.300 Flight instructor certificate

(a) General

An instructor shall only carry out flight instruction in a sailplane if he or she:

- (1) holds:
  - (i) an SPL including the privileges, ratings and certificates for which flight instruction is to be provided;
  - (ii) a sailplane flight instructor (FI(S)) certificate appropriate to the instruction carried out, and issued in accordance with this Subpart;
- (2) is entitled to act as PIC in the sailplane during flight instruction.
- (b) Instruction provided outside the territory of the Member States
  - (1) By way of derogation from paragraph (a)(1), in the case of flight instruction provided during a training course approved in accordance with this Annex (Part-SFCL) outside the territory for which Member States are responsible under the Chicago Convention, the competent authority shall issue a flight instructor certificate to an applicant who holds a sailplane pilot licence that is compliant with Annex 1 to the Chicago Convention, provided that the applicant:
    - holds at least a licence including, where relevant, privileges, ratings or certificates equivalent to those for which he or she is authorised to instruct;
    - (ii) complies with the requirements established in this Subpart for the issue of the FI(S) certificate with the relevant instructional privileges;
    - (iii) demonstrates to the competent authority an adequate level of knowledge of European aviation safety rules to be able to exercise his or her instructional privileges in accordance with this Annex.
  - (2) The certificate shall be limited to the provision of flight instruction:
    - (i) outside the territory for which Member States are responsible under the Chicago Convention;
    - (ii) to a student pilot who has sufficient knowledge of the language in which flight instruction is provided.

#### Section 2

## Flight instructor certificate for sailplanes – FI(S)

# SFCL.315 FI(S) certificate – Privileges and conditions

- (a) Subject to compliance of the applicants with point SFCL.320 and with the following conditions, an FI(S) certificate shall be issued with privileges to conduct flight instruction for:
  - (1) an SPL;

- (2) additional sailplane privileges in accordance with point SFCL.150(e);
- (3) launching methods in accordance with point SFCL155, provided that the applicant has completed as PIC:
  - (i) in the case of aerotow launch, at least 30 launches; or
  - (ii) in the case of winch launch, at least 50 launches;
- (4) additional TMG privileges in accordance with point SFCL.150(b), provided that the applicant has:
  - (i) completed at least 30 hours of flight time as PIC on TMGs;
  - (ii) completed the training as specified in point SFCL.330(b)(2);
  - (iii) demonstrated the ability to instruct on TMGs to an FI(S) who is qualified in accordance with paragraph (7) and nominated by the head of training of the ATO or the DTO;
- (5) basic aerobatic, advanced aerobatic or sailplane cloud flying privileges or the sailplane towing or the banner towing rating, provided that the applicant:
  - (i) in the case of instruction for basic aerobatic or advanced aerobatic privileges, holds advanced aerobatic privileges in accordance with point SFCL.200(c);
  - (ii) has demonstrated the ability to instruct for the relevant privileges or rating to an FI(S) who is qualified in accordance with paragraph (a)(7) and nominated by the head of training of an ATO or a DTO;
- (6) TMG flight at night, provided that the applicant:
  - (i) complies with the night experience requirement in point SFCL.160(e)(2);
  - (ii) has demonstrated the ability to instruct on TMGs at night to an FI(S) who is qualified in accordance with paragraph (7) and nominated by the head of training of an ATO or a DTO;
- (7) an FI(S) certificate, provided that the applicant has:
  - (i) completed at least 50 hours or 150 launches of flight instruction in sailplanes;
  - (ii) in accordance with the procedures established for that purpose by the competent authority, demonstrated the ability to instruct for the FI(S) certificate to an FI(S) who is qualified in accordance with this paragraph and nominated by the head of training of an ATO or a DTO.
- (b) The privileges listed in paragraph (a) shall include the privileges to conduct flight instruction for:
  - (1) the issue of the relevant licence, privileges, ratings or certificate; and
  - (2) the revalidation, renewal or compliance with the relevant recency requirements of this Annex, as applicable.

## SFCL.320 FI(S) certificate – Prerequisites and requirements

Applicants for an FI(S) certificate shall:

- (a) be at least 18 years of age;
- (b) comply with the requirements of point (a)(1)(i) and paragraph (2) of point SFCL.300;
- (c) have completed 100 hours of flight time and 200 launches as PIC on sailplanes;
- (d) have completed an instructor training course in accordance with point SFCL.330 at an ATO or a DTO; and
- (e) have passed an assessment of competence in accordance with point SFCL.345.

## SFCL.325 FI(S) competencies and assessment

Applicants for an FI(S) certificate shall be trained to achieve the following competencies:

- (a) prepare resources;
- (b) create a climate conducive to learning;
- (c) present knowledge;
- (d) integrate threat and error management (TEM) and crew resource management (CRM);
- (e) manage time to achieve training objectives;
- (f) facilitate learning;
- (g) assess trainee performance;
- (h) monitor and review progress;
- (i) evaluate training sessions; and
- (j) report outcome.

#### SFCL.330 FI(S) – Training course

- (a) Applicants for an FI(S) certificate shall first pass a specific pre-entry assessment at an ATO or a DTO, which shall take place within the 12 months preceding the start of the training course, to assess their ability to undertake the course.
- (b) The FI(S) training course shall include:
  - (1) on sailplanes, excluding TMGs:
    - (i) the elements specified in point SFCL.325;
    - (ii) 25 hours of teaching and learning;
    - (iii) 30 hours of theoretical knowledge instruction, including progress tests;
    - (iv) at least six hours, of which a maximum of three hours may be completed in TMGs, or 20 launches of flight instruction;
  - (2) additionally, if the privileges of the FI(S) certificate will include the privileges as specified in point SFCL.315(a)(4) and (a)(6), at least six hours of dual flight instruction on TMGs.
- (c) Applicants who already hold an instructor certificate in accordance with Annex III (Part-BFCL) to Regulation (EU) 2018/395 or with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 shall be fully credited towards the requirement in paragraph (b)(1)(ii).
- (d) When applying for an FI(S) certificate, a pilot who holds or has held an FI(A), (H) or (As) shall be credited with 18 hours towards the requirements in paragraph (b)(1)(iii).

#### SFCL.345 FI(S) – Assessment of competence

- (a) Applicants for the issue of an FI(S) certificate shall pass an assessment of competence to demonstrate to an examiner qualified in accordance with point SFCL.415(c) the ability to instruct a student pilot to the level required for the issue of an SPL.
- (b) The assessment shall include:
  - the demonstration of the competencies described in point SFCL.325, during pre-flight, post-flight and theoretical knowledge instruction;
  - (2) oral theoretical examinations on the ground, pre-flight and post-flight briefings, and in-flight demonstrations in sailplanes;
  - (3) exercises adequate to evaluate the instructor's competencies.

(c) The assessment of competence for the initial issue of an FI(S) certificate shall be conducted in sailplanes, excluding TMGs.

## SFCL.350 FI(S) – Restricted privileges

- (a) An FI(S) shall have his or her privileges limited to conducting flight instruction under the supervision of an unrestricted FI(S) nominated by the ATO or the DTO for this purpose, in the following cases:
  - (1) for the issue of an SPL;
  - (2) for extending the privileges of an SPL to additional sailplane or TMG privileges in accordance with point SFCL150;
  - (3) for extending the privileges of an SPL to additional launching methods in accordance with point SFCL155; and
  - (4) for basic aerobatic, advanced aerobatic or sailplane cloud flying privileges or for the sailplane towing or banner towing rating.
- (b) Whilst conducting training under supervision, in accordance with paragraph (a), the FI(S) shall not have the privilege to authorise a student pilot to conduct his or her first solo flight or first solo cross-country flight.
- (c) The limitations in (a) and (b) shall be removed from the FI(S) certificate after the FI(S) has completed at least 15 hours or 50 launches of flight instruction covering all phases of a sailplane flight. In the case of a restricted FI(S) who complied with point SFCL.330(b)(2), 5 out of those 15 hours may be completed in TMGs, and 15 out of those 50 launches may be replaced by take-offs and landings in TMGs.

### SFCL.360 FI(S) certificate – Recency requirements

- (a) An FI(S) certificate holder shall only exercise the privileges of his or her certificate if before the planned exercise of those privileges he or she has:
  - (1) within the last three years, completed:
    - (i) instructor refresher training at an ATO, a DTO, or a competent authority during which the holder shall receive theoretical knowledge instruction for refreshing and updating the knowledge relevant for sailplane instructors; and
    - (ii) when providing flight instruction as FI(S), at least:
      - (A) 30 hours; or
      - (B) 60 launches or take-offs and landings; and
  - (2) within the last nine years and in accordance with the procedures established for that purpose by the competent authority, demonstrated the ability to instruct on sailplanes to an FI(S) who is qualified in accordance with point SFCL.315(a)(7) and nominated by the head of training of an ATO or a DTO.
- (b) The hours flown as an FE(S) during skill tests, proficiency checks and assessments of competence shall be fully credited towards the requirement in paragraph (a)(1)(ii).
- (c) If the FI(S) certificate holder has failed to complete the instruction flight under supervision to the satisfaction of the FI (S) in accordance with paragraph (a)(2), he or she shall not exercise the privileges of the FI(S) certificate until he or she has successfully completed an assessment of competence in accordance with point SFCL.345.
- (d) To resume the exercise of the privileges of the FI(S) certificate, an FI(S) certificate holder who does not comply with all the requirements in paragraph (a) shall comply with the requirements of paragraph (a)(1)(i) and of point SFCL.345.

## SUBPART FE

## FLIGHT EXAMINERS

Section 1

## **General requirements**

### SFCL.400 Sailplane flight examiner certificates

(a) General

An examiner shall only carry out skill tests, proficiency checks or assessments of competence in accordance with this Annex if he or she:

- (1) holds:
  - (i) an SPL including privileges, ratings and certificates for which he or she is authorised to conduct skill tests, proficiency checks or assessments of competence, and the privileges to instruct for them;
  - (ii) an FE(S) certificate including privileges appropriate to the skill test, proficiency check or assessment of competence conducted, issued in accordance with this Subpart;
- (2) is entitled to act as PIC in a sailplane during the skill test, proficiency check or assessment of competence.
- (b) Examinations conducted outside the territory of the Member States
  - (1) By way of derogation from paragraph (a)(1), in the case of skills tests and proficiency checks performed outside the territory for which Member States are responsible under the Chicago Convention, the competent authority shall issue an examiner certificate to an applicant who holds a sailplane pilot licence that is compliant with Annex 1 to the Chicago Convention, provided that the applicant:
    - (i) holds at least a licence including, where relevant, privileges, ratings or certificates equivalent to those for which he or she is authorised to conduct skill tests or proficiency checks;
    - (ii) complies with the requirements established in this Subpart for the issue of the relevant examiner certificate;
    - (iii) demonstrates to the competent authority an adequate level of knowledge of Union aviation safety rules to be able to exercise the examiner privileges in accordance with this Annex.
  - (2) The certificate referred to in paragraph (1) shall be limited to performing skill tests and proficiency checks:
    - (i) outside the territory for which Member States are responsible under the Chicago Convention; and
    - (ii) to a pilot who has sufficient knowledge of the language in which the test/check is provided.

#### SFCL.405 Limitation of privileges in case of vested interests

A sailplane examiner shall not conduct:

- (a) a skill test or assessment of competence of an applicant for the issue of a licence, rating or certificate to whom he or she has provided more than 50 % of the required flight instruction for the licence, rating or certificate for which the skill test or assessment of competence is taken; or
- (b) a skill test, proficiency check or assessment of competence whenever he or she feels that his or her objectivity may be affected.

## SFCL.410 Conduct of skill tests, proficiency checks and assessments of competence

- (a) When conducting skill tests, proficiency checks and assessments of competence, a sailplane examiner shall do all of the following:
  - (1) ensure that communication with the applicant can be established without language barriers;
  - (2) verify that the applicant complies with all the qualification, training and experience requirements of this Annex for the issue, revalidation or renewal of the licence, privileges, rating or certificate for which the skill test, proficiency check or assessment of competence is taken;
  - (3) make the applicant aware of the consequences of providing incomplete, inaccurate or false information related to his or her training and flight experience.
- (b) After completion of the skill test, proficiency check or assessment of competence, the sailplane examiner shall:
  - (1) inform the applicant of the results of the skill test, proficiency check or assessment of competence;
  - (2) in the event of a pass in an assessment of competence for the revalidation or renewal, endorse the new expiry date on the applicant's licence or certificate, if specifically authorised for that purpose by the competent authority that is responsible for the applicant's licence;
  - (3) provide the applicant with a signed report of the skill test, proficiency check or assessment of competence and submit without undue delay copies of the report to the competent authority that is responsible for the applicant's licence, and to the competent authority that issued the examiner certificate. The report shall include:
    - (i) a declaration that the sailplane examiner has received information from the applicant regarding his or her experience and instruction, and found that experience and instruction comply with the applicable requirements of this Annex;
    - (ii) confirmation that all the required manoeuvres and exercises have been completed, as well as information on the verbal theoretical knowledge examination, when applicable. If an item of those categories has been failed, the examiner shall record the reasons for this assessment;
    - (iii) the result of the skill test, proficiency check or assessment of competence;
    - (iv) a declaration that the sailplane examiner has reviewed and applied the national procedures and requirements of the applicant's competent authority if the competent authority that is responsible for the applicant's licence is not the one that issued the examiner's certificate;
    - (v) a copy of the sailplane examiner certificate containing the scope of his or her privileges as sailplane examiner in the case of skill tests, proficiency checks or assessments of competence of an applicant whose competent authority is not the one that issued the examiner's certificate.
- (c) The sailplane examiner shall maintain the records for five years with details of all skill tests, proficiency checks and assessments of competence performed and their results.
- (d) Upon request by the competent authority that is responsible for the sailplane examiner certificate, or the competent authority that is responsible for the applicant's licence, the sailplane examiner shall submit all records and reports, and any other information, as required, for oversight activities.

#### Section 2

# Flight examiner certificate for sailplanes – FE(S)

## SFCL.415 FE(S) certificate – Privileges and conditions

Subject to compliance of the applicant with point SFCL.420 and with the following conditions, an FE(S) certificate shall be issued upon application with privileges to conduct:

(a) skill tests and proficiency checks for the SPL, provided that the applicant has completed, on sailplanes, excluding TMGs, 300 hours of flight time as a pilot, including 150 hours or 300 launches of flight instruction;

- (b) skill tests for the extension of the SPL privileges to TMG in accordance with point SFCL.150(e), provided that the applicant has completed 300 hours of flight time on sailplanes, including 50 hours of flight instruction in TMGs;
- (c) assessments of competence for the issue of FI(S) certificates on sailplanes, provided that the applicant has:
  - (1) completed at least 500 hours of flight time as pilot on sailplanes, including, if the privileges of the FE(S) certificate will be exercised in:
    - (i) sailplanes, excluding TMGs, at least 10 hours or 30 launches instructing the applicant for an FI(S) certificate in sailplanes, excluding TMGs;
    - (ii) TMGs, at least 10 hours or 30 take-offs and landings instructing the applicant for an FI(S) certificate in TMGs;
  - (2) received specific training during an examiner standardisation course in accordance with point SFCL.430.

### SFCL.420 FE(S) certificate – Prerequisites and requirements

Applicants for an FE(S) certificate shall:

- (a) comply with the requirements of point (a)(1)(i) and paragraph (a)(2) of point SFCL.400;
- (b) have completed the FE(S) standardisation course in accordance with point SFCL.430;
- (c) have completed an assessment of competence in accordance with point SFCL.445;
- (d) demonstrate relevant background related to the privileges of the FE(S) certificate; and
- (e) demonstrate that they have not been subject to any sanctions, including the suspension, limitation or revocation of any of his or her licences, ratings or certificates issued in accordance with this Annex, with Annex I (Part-FCL) to Regulation (EU) No 1178/2011, or with Annex III (Part-BFCL) to Regulation (EC) No 2018/395, for non-compliance with Regulation (EU) 2018/1139 and its delegated and implementing acts during the last three years.

#### SFCL.430 FE(S) certificate – Standardisation course

- (a) Applicants for an FE(S) certificate shall take a standardisation course which is provided either by the competent authority or by an ATO or a DTO and approved by that competent authority.
- (b) The standardisation course shall be tailored to the sailplane flight examiner privileges sought and shall consist of theoretical and practical instruction, including, at least:
  - the conduct of two skill tests, proficiency checks or assessments of competence for the SPL or associated ratings or certificates;
  - (2) instruction on the applicable requirements of this Annex and the applicable air operations requirements, the conduct of skill tests, proficiency checks and assessments of competence, and their documentation and reporting;
  - (3) a briefing on the following:
    - (i) national administrative procedures;
    - (ii) requirements for the protection of personal data;
    - (iii) examiner's liability;
    - (iv) examiner's accident insurance;
    - (v) national fees; and
    - (vi) information on how to access the information contained in points (i) to (v) when conducting skill tests, proficiency checks or assessments of competence of an applicant whose competent authority is not the one that issued the examiner certificate.

(c) An FE(S) certificate holder shall not conduct skill tests, proficiency checks or assessments of competence of an applicant whose competent authority is not the one that issued the examiner certificate, unless he or she has reviewed the latest available information containing the relevant national procedures of the applicant's competent authority.

### SFCL.445 FE(S) certificate – Assessment of competence

An applicant for the initial issue of an FE(S) certificate shall demonstrate his or her competence as an FE(S), to an inspector from the competent authority or to a senior examiner specifically authorised to do so by the competent authority that is responsible for the FE(S) certificate. During the assessment of competence, the applicant shall conduct a skill test, proficiency check or assessment of competence, including briefing, conduct of the skill test, proficiency check or assessment of the person to whom the test, check or assessment is given, debriefing and recording documentation.

## SFCL.460 FE(S) certificate - Validity, revalidation and renewal

- (a) An FE(S) certificate shall be valid for five years.
- (b) An FE(S) certificate shall be revalidated if its holder has:
  - during the validity period of the FE(S) certificate, completed an examiner refresher course which is provided either by the competent authority or by an ATO or a DTO and approved by that competent authority, during which the holder shall receive theoretical knowledge instruction for refreshing and updating the knowledge relevant for sailplane examiners;
  - (2) within the last 24 months preceding the end of the validity period of the certificate, demonstrated the ability to conduct skill tests, proficiency checks or assessments of competence to an inspector from the competent authority or an examiner specifically authorised to do so by the competent authority that is responsible for the FE(S) certificate.
- (c) An FE(S) certificate holder who also holds one or more examiner certificates for other aircraft categories in accordance with Annex I (Part-FCL) to Regulation (EU) No 1178/2011 or with Annex III (Part-BFCL) to Regulation (EU) 2018/395 may achieve combined revalidation of all examiner certificates held, in agreement with the competent authority.
- (d) If an FE(S) certificate has expired, its holder shall comply with the requirements of paragraph (b)(1) and of point SFCL.445 before he or she can resume the exercise of the privileges of the FE(S) certificate.
- (e) An FE(S) certificate shall only be revalidated or renewed if the applicant demonstrates continued compliance with the requirements of point SFCL.410 as well as with the requirements of point SFCL.420(d) and (e).'.

## COMMISSION IMPLEMENTING REGULATION (EU) 2020/359

#### of 4 March 2020

amending Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council

(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 (<sup>1</sup>), and in particular Articles 23 and 27 thereof,

#### Whereas:

- (1) Commission Regulation (EU) No 1178/2011 (<sup>2</sup>) lays down the requirements for pilots who are involved in the operation of aircraft as specified in points (b)(i) and (ii) of Article 2(1) of Regulation (EU) 2018/1139.
- (2) In light of the specific nature of flight crew licensing for balloons and sailplanes, dedicated licensing requirements should be laid down in separate regulations, namely in Commission Regulation (EU) 2018/395 (<sup>3</sup>) and Commission Implementing Regulation (EU) 2018/1976 (<sup>4</sup>).
- (3) At the same time, the licensing requirements for balloon and sailplane pilot licences laid down in Annex I (Part-FCL) to Regulation (EU) No 1178/2011 should be deleted and some requirements of Annex I (Part-FCL) that address cross-domain issues, such as crediting provisions between balloon or sailplane pilot licences and licences for other aircraft categories, should be revised in light of the new licensing requirements for balloon and sailplane pilots.
- (4) The requirements of Annex IV (Part-MED) Annex VI (Part-ARA), Annex VII (Part-ORA) and Annex VIII (Part-DTO) to Regulation (EU) No 1178/2011 should continue to apply to balloon and sailplane flight crew licensing.
- (5) In order to further improve aviation safety, pilots that are engaged in aerial sport and recreational activities should be encouraged to obtain privileges for flying in accordance with instrument flight rules ('IFR'). Therefore, the existing rules concerning IFR privileges should be adapted by introducing the basic instrument rating ('BIR') in Annex I (Part-FCL) to Regulation (EU) No 1178/2011. The BIR should be specifically tailored to the needs of pilots who are engaged in aerial sport and recreational flying activities as regards the content of their training and the scope of their privileges.
- (6) With the introduction of the BIR, the en route instrument rating ('EIR') in point FCL.825 of Annex I (Part-FCL) to Regulation (EU) No 1178/2011 becomes redundant and therefore it should be deleted. However, the existing EIR holders should be entitled to continue to exercise their privileges and should receive credits from their EIR when they seek to obtain a BIR. It should also be possible to continue an on-going training for an EIR that commenced prior to the application of this Regulation and to complete it as training for a BIR.

<sup>(&</sup>lt;sup>1</sup>) OJ L 212, 22.8.2018, p. 1.

<sup>(2)</sup> Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p. 1).

<sup>&</sup>lt;sup>(3)</sup> Commission Regulation (EU) 2018/395 of 13 March 2018 laying down detailed rules for the operation of balloons pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 71, 14.3.2018, p. 10).

<sup>(\*)</sup> Commission Implementing Regulation (EU) 2018/1976 of 14 December 2018 laying down detailed rules for the operation of sailplanes pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council (OJ L 326, 20.12.2018, p. 64).

- (7) Technical update to Regulation (EU) No 1178/2011 should be made on basis of lessons learned in particular in the area of Performance Based Navigation (PBN), Upset Prevention and Recovery Training (UPRT) and instructor and examiner qualifications.
- (8) The measures provided for in this Regulation are based on Opinion No 01/2019 <sup>(3)</sup> of the European Union Aviation Safety Agency in accordance with point (b) of Article 75(2) and Article 76(1) of Regulation (EU) 2018/1139.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 127 of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 1178/2011 is amended as follows:

(1) Article 1 is replaced by the following:

'Article 1

### Subject matter

- 1. This Regulation lays down detailed rules for:
  - (a) different ratings for pilot licences, the conditions for issuing, maintaining, amending, limiting, suspending or revoking pilot licences, the privileges and responsibilities of the holders of pilot licences, as well as the conditions for the conversion of existing national pilot licences and of national flight engineer licences into pilot licences;
  - (b) the certification of persons who are responsible for providing flight training or flight simulation training and for assessing pilots' skills;
  - (c) different medical certificates for pilots, the conditions for issuing, maintaining, amending, limiting, suspending or revoking medical certificates, the privileges and responsibilities of the holders of medical certificates as well as the conditions for the conversion of national medical certificates into mutually recognised medical certificates;
  - (d) the certification of aero-medical examiners, as well as the conditions under which general medical practitioners may act as aero-medical examiners;
  - (e) the periodical aero-medical assessment of cabin crew members, as well as the qualifications of persons who are responsible for that assessment;
  - (f) the conditions for issuing, maintaining, amending, limiting, suspending or revoking cabin crew attestations, as well as the privileges and responsibilities of the holders of cabin crew attestations;
  - (g) the conditions for issuing, maintaining, amending, limiting, suspending or revoking certificates of pilot training organisations and of aero-medical centres involved in the qualification and aero-medical assessment of civil aviation aircrew;
  - (h) the requirements for the certification of flight simulation training devices and for organisations that operate and use those devices;
  - (i) the requirements for the administration and management system to be fulfilled by the Member States, the European Union Aviation Safety Agency ('EASA') and organisations in relation to the rules referred to in points (a) to (h).
- 2. Articles 11b and 11c of this Regulation as well as Annex IV (Part-MED), Annex VI (Part-ARA), Annex VII (Part-ORA) and Annex VIII (Part-DTO) to this Regulation shall apply to pilot licences for balloons and sailplanes.'

<sup>(5)</sup> Easier access for GA pilots to IFR flying & Revision of the balloon and sailplane licensing requirements, (Opinion No 01/2019 (A) & (B), 19.02.2019), available at: https://www.easa.europa.eu/document-library/opinions

- (2) in Article 2, paragraph 19 is replaced by the following:
  - '(19) "Flight instructor (FI)" means an instructor with the privileges to provide training in an aircraft in accordance with Subpart J of Annex I (Part-FCL) to this Regulation, Subpart FI of Annex III (Part-BFCL) to Regulation (EU) 2018/395 (\*), or Subpart FI of Annex III (Part-SFCL) to Implementing Regulation (EU) 2018/1976 (\*\*);
  - (\*) Commission Regulation (EU) 2018/395 of 13 March 2018 laying down detailed rules for the operation of balloons pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 71, 14.3.2018, p. 10).
  - (\*\*) Commission Implementing Regulation (EU) 2018/1976 of 14 December 2018 laying down detailed rules for the operation of sailplanes pursuant to Regulation (EU) 2018/1139 of the European Parliament and of the Council (OJ L 326, 20.12.2018, p. 64).';
- (3) In article 4, paragraph 8, '8 April 2021' is replaced by '8 September 2021'.
- (4) the following Article 4c is inserted:

#### 'Article 4c

## Transitional measures for holders of an en route instrument rating

- 1. Up to and including 8 September 2022, holders of an en route instrument rating ('EIR') set out in point FCL.825 of Annex I (Part-FCL) shall:
  - (a) be entitled to continue to exercise the privileges of their EIR;
  - (b) receive revalidation or renewal of their EIR, in accordance with point FCL.825(g) of Commission Delegated Regulation (EU) (\*);
  - (c) be entitled to receive full credit towards the training requirements in point FCL.835(c)(2)(i) and (ii) of Annex I (Part-FCL), when applying for the issue of a basic instrument rating (BIR) in accordance with point FCL.835 of Annex I (Part-FCL); and
  - (d) receive full credit as established for EIR holders in Annex I (Part-FCL).
- 2. As from 8 September 2021, training courses for an EIR referred to in paragraph 1, that have commenced prior to that date, can be continued and shall be regarded as training courses for a BIR. Based on an assessment of the applicant, the approved training organisation responsible for the BIR training course shall determine the amount of EIR training to be credited towards the issue of the BIR.
- 3. Applicants for a BIR who hold an EIR or have passed the theoretical knowledge examination for an EIR in accordance with point FCL.825(d) prior to 8 September 2021 shall receive full credit towards the requirements for the theoretical knowledge instruction and examination for the BIR.

(\*) Commission Delegated Regulation (EU) of 4 March 2020 (not yet published in the Official Journal).';

(5) Article 11c is replaced by the following:

'Article 11c

### **Transitional measures**

Member States shall:

(a) by 8 April 2021 at the latest, transfer to EASA all records related to the oversight of organisations that provide training for pilot licences in accordance with Regulation (EU) 2018/395 and Implementing Regulation (EU) 2018/1976 and for which EASA is the competent authority in accordance with Article 78 of Regulation (EU) 2018/1139 of the European Parliament and of the Council (\*);

- (b) in coordination with EASA, conclude, certification processes initiated before 8 April 2020 and issue the certificate following which EASA assumes all its responsibilities as a competent authority for those certified organisations.
- (\*) Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1).';
- (6) in Article 12, point (2a) is deleted;
- (7) in Article 12(4), '20 June 2020' is replaced by '20 June 2021'
- (8) Annex I (Part-FCL) is amended in accordance with Annex I to this Regulation;
- (9) Annex IV (Part-MED) is amended in accordance with Annex II to this Regulation;
- (10) Annex VI (Part-ARA) is amended in accordance with Annex III to this Regulation;
- (11) Annex VII (Part-ORA) is amended in accordance with Annex IV to this Regulation;
- (12) Annex VIII (Part-DTO) is amended in accordance with Annex V to this Regulation.

# Article 2

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

- 2. This Regulation shall apply from 8 April 2020.
- 3. By way of derogation from paragraph 2, the following provisions shall apply from 8 September 2021:
  - (a) points (1)(e), (4)(b), (5) to (7), (32), (34), (36)(d), (40)(a), (41); (42), (44), (46) to (48), (52)(f), (53)(a) to (53)(c) (53) (e), (53)(f), (54), (55), (56)(a) to (56)(c) and (57) of Annex I;
  - (b) point (b) of Annex II;
  - (c) point (10)(d)(ii) of Annex III.
- 4. By way of derogation from paragraph 2, Article 1 point (7) and points (49), (53)(d), (58)(b), (58)(d) and (58)(e) of Annex I shall apply from the day of entry into force of this Regulation.

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

Done at Brussels, 4 March 2020.

For the Commission The President Ursula VON DER LEYEN

## L 67/86

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#### ANNEX I

Annex I (Part-FCL) to Commission Regulation (EU) No 1178/2011 is amended as follows:

- (1) Point FCL.010 is amended as follows:
  - (a) the definition of 'airship' is replaced by the following:

"Airship" means a power-driven lighter-than-air aircraft, with the exception of hot-air airships, which are considered to be balloons in accordance with Article 2(7) of Commission Regulation (EU) 2018/395.';

(b) the definition of 'flight time' is replaced by the following:

"Flight time":

for aeroplanes, touring motor gliders and powered-lift aircraft, it means the total time from the moment an aircraft first moves for the purpose of taking off until the moment it finally comes to rest at the end of the flight;

for helicopters, it means the total time from the moment a helicopter's rotor blades start turning until the moment the helicopter finally comes to rest at the end of the flight, and the rotor blades are stopped;

for airships, it means the total time from the moment an airship is released from the mast for the purpose of taking off until the moment the airship finally comes to rest at the end of the flight, and is secured on the mast.';

(c) the definition of 'powered sailplane' is replaced by the following:

"Powered sailplane" means a sailplane equipped with one or more engines that has, with engines inoperative, the characteristics of a sailplane.;

(d) the definition of 'touring motor glider' is replaced by the following:

"Touring motor glider (TMG)" means, unless otherwise specified following the certification process in accordance with Annex I (Part 21) to Regulation (EU) No 748/2012, a specific class of powered sailplanes that has an integrally mounted, non-retractable engine and a non-retractable propeller. It shall be capable of taking off and climbing under its engine power according to its flight manual.';

- (e) the following definitions are inserted:
  - (i) "En route IFR flight" means the phase of an IFR flight that commences after the completion of an IFR departure procedure and finishes when commencing an IFR approach procedure.'; and
  - (ii) "Limited panel instrument flight" means attitude interpretation by reference to standby instruments interpretation after the loss of main attitude and heading reference system.';
- (f) the following definitions are deleted:

'Class of balloon' and

'Group of balloons';

- (2) point FCL.015 in amended as follows:
  - (a) paragraph (a) is replaced by the following:
    - '(a) An application for the issue, revalidation or renewal of pilot licences and associated ratings and certificates as well as any amendment thereto shall be submitted to the competent authority in a form and manner established by that authority. The application shall be accompanied by evidence that applicants comply with the requirements for the issue, revalidation or renewal of the licence or certificate as well as associated ratings or endorsements established in this Annex (Part-FCL) and in Annex IV (Part-MED).';
  - (b) paragraph (b) is replaced by the following:
    - (b) Unless otherwise specified in this Annex, any limitation or extension of the privileges granted by a licence, rating or certificate shall be endorsed in the licence or certificate by the competent authority.';
  - (c) paragraph (d) is replaced by the following:
    - '(d) A licence holder shall submit applications in accordance with paragraph (a) to the competent authority designated by the Member State in which his or her licence was issued in accordance with this Annex (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 or with Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable.';

- (d) the following new paragraphs (e) and (f) are added:
  - '(e) The holder of a licence that has been issued in accordance with this Annex (Part-FCL) may apply to the competent authority designated by another Member State for a change of competent authority relating to all licences held, as specified in paragraph (d).
  - (f) For the issue of a licence, rating or certificate the applicant shall apply not later than 6 months after having succeeded at the skill test or assessment of competence.';
- (3) in point FCL.020, paragraph (b) is replaced by the following:
  - (b) Before his or her first solo flight, a student pilot shall be at least 16 years of age.';
- (4) point FCL.025(c)(1) is amended as follows:
  - (a) paragraph (i) is replaced by the following:
    - (i) for the issue of a light aircraft pilot licence or a private pilot licence, for a period of 24 months;';
  - (b) paragraphs (ii) and (iii) are replaced by the following:
    - (ii) for the issue of a commercial pilot licence or instrument rating (IR), for a period of 36 months;
    - (iii) for the issue of a basic instrument rating (BIR), for an unlimited duration.

The periods in paragraphs (i) and (ii) shall be counted from the day on which the pilots have successfully completed the theoretical knowledge examination, in accordance with paragraph (b)(2).';

- (5) in point FCL.030, the following paragraph (c) is added:
  - (c) For the issue of a BIR, the applicant for a skill test must first complete all training modules and be recommended for the skill test by an ATO. His or her training records shall be made available to the examiner, by the ATO.';
- (6) in point FCL.035, paragraph (b) is replaced by the following:
  - (b) Crediting of theoretical knowledge
    - (1) Applicants that have passed the theoretical knowledge examination for an airline transport pilot licence shall be credited towards the requirements for the theoretical knowledge for the light aircraft pilot licence, the private pilot licence, the commercial pilot licence and, except in the case of helicopters, the IR and the BIR in the same category of aircraft.
    - (2) Applicants that have passed the theoretical knowledge examination for a commercial pilot licence shall be credited towards the requirements for the theoretical knowledge for:
      - (i) the light aircraft pilot licence in the same category of aircraft;
      - (ii) the private pilot licence in the same category of aircraft; and
      - (iii) the subject 'communications' for the BIR. This credit shall include the IFR part of the subject 'communications' only if that subject was completed in accordance with point FCL.310, as applicable as of 20 December 2019.
    - (3) Holders of an IR or applicants that have passed the IR theoretical knowledge examination for a category of aircraft shall be credited towards the requirements for the theoretical knowledge instruction and examination for:
      - (i) the IR in another category of aircraft; and
      - (ii) the BIR.
    - (4) Holders of a pilot licence shall be credited towards the requirements for theoretical knowledge instruction and examination for a licence in another category of aircraft in accordance with Appendix 1 to this Part. This credit also applies to applicants for a pilot licence who have already successfully completed the theoretical knowledge examinations for the issue of that licence in another category of aircraft, as long as the theoretical knowledge examination is within the validity period specified in point FCL.025(c).
    - (5) By way of derogation from paragraph (b)(3), holders of an IR(A) who have completed a competency-based modular IR(A) course shall be fully credited towards the requirements for theoretical knowledge instruction and examination for an IR in another category of aircraft only if they have also passed the theoretical knowledge instruction and examination for the IFR part of the course required in accordance with point FCL.720.A(b)(2)(i).';

- (7) point FCL.055 is amended as follows:
  - (a) in paragraph (d), the introductory sentence is replaced by the following:
    - '(d) Specific requirements for holders of an instrument rating (IR). By way of derogation from the paragraphs above, holders of an IR shall have demonstrated the ability to use the English language at the appropriate proficiency level as defined in Appendix 2 to this Annex.';
  - (b) paragraph (e) is replaced by the following:
    - '(e) The demonstration of language proficiency and the use of the English language for IR holders shall be done through a method of assessment established by any competent authority.';
- (8) point FCL.060 is amended as follows:
  - (a) paragraph (a) is deleted;
  - (b) in paragraph (b), the introductory sentence is replaced by the following:
    - (b) Aeroplanes, helicopters, powered-lift aircraft and airships. A pilot shall not operate an aircraft in commercial air transport or to carry passengers:';
- (9) point FCL.065 is amended as follows:
  - (a) paragraph (b) is replaced by the following:
    - (b) Age 65. Holders of a pilot licence who has attained the age of 65 years shall not act as a pilot of an aircraft that is engaged in commercial air transport.';
  - (b) paragraph (c) is deleted;
- (10) point FCL.100 is replaced by the following:

### 'FCL.100 LAPL - Minimum age

Applicants for the LAPL for aeroplanes or helicopters shall be at least 17 years old.';

(11) point FCL.120 is replaced by the following:

## 'FCL.120 LAPL – Theoretical knowledge examination

Applicants for an LAPL shall demonstrate a level of theoretical knowledge appropriate to the privileges granted, through examinations on the following:

- (a) common subjects:
- Air law,
- Human performance,
- Meteorology,
- Communications, and
- Navigation.
- (b) specific subjects concerning the different aircraft categories:
- Principles of flight,
- Operational procedures,
- Flight performance and planning, and
- Aircraft general knowledge.';
- (12) in point FCL.110.A, paragraph (b) is replaced by the following:
  - (b) Specific requirements for applicants who hold an SPL issued in accordance with Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, including privileges to fly TMGs. Applicants for an LAPL(A) who hold an SPL with the privileges to fly TMGs shall have completed at least 21 hours of flight time on TMGs after the endorsement of the TMG privileges and shall comply with the requirements of point FCL.135.A(a) on aeroplanes.';

- (13) in point FCL.135.A, the following paragraph (c) is added:
  - '(c) Applicants for the extension of privileges of the LAPL(A) to TMG who also hold an SPL in accordance with Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, including the privileges to fly on TMGs, shall receive full credits towards the requirements in paragraph (a).';
- (14) Sections 4 and 5 of Subpart B are deleted;
- (15) the title of Subpart C is replaced by the following:

## 'PRIVATE PILOT LICENCE (PPL)';

(16) point FCL.200 is replaced by the following:

## 'FCL.200 Minimum age

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Applicants for a PPL shall be at least 17 years old.';

- (17) in point FCL.210, paragraphs (a) and (b) are replaced by the following:
  - (a) Applicants for a PPL shall complete a training course at an ATO or a DTO.
  - (b) The course shall include theoretical knowledge and flight instruction appropriate to the privileges of the PPL applied for.';
- (18) point FCL.215 is replaced by the following:

## FCL.215 Theoretical knowledge examination

Applicants for a PPL shall demonstrate a level of theoretical knowledge appropriate to the privileges granted through examinations in the following subjects:

- (a) common subjects:
- Air law,
- Human performance,
- Meteorology,
- Communications; and
- Navigation.
- (b) specific subjects concerning the different aircraft categories:
- Principles of flight,
- Operational procedures,
- Flight performance and planning, and
- Aircraft general knowledge.';
- (19) point FCL.235 is amended as follows:
  - (a) paragraph (a) is replaced by the following:
    - '(a) Through the completion of a skill test, applicants for a PPL shall demonstrate the ability to perform as PIC on the appropriate aircraft category, their knowledge of relevant procedures and manoeuvres with the competency appropriate to the privileges granted.';
  - (b) paragraph (b) is replaced by the following:
    - (b) Applicants for the skill test shall have received flight instruction on the same class or type of aircraft to be used for the skill test.';
- (20) in point FCL.210.A, paragraph (c) is amended as follows:
  - (a) the introductory sentence is replaced by the following:
    - '(c) Specific requirements for applicants who hold an SPL issued in accordance with Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, including privileges to fly TMGs. Applicants for a PPL(A) who hold an SPL with the privileges to fly TMGs shall have completed.';

- (b) subparagraph (1) is replaced by the following:
  - (1) at least 24 hours of flight time on TMGs after endorsement of the TMG privileges; and';
- (21) in point FCL.210.As, paragraph (b) is replaced by the following:
  - '(b) Applicants who hold a BPL issued in accordance with Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and are qualified to fly hot-air airships shall be credited with 10 % of their total flight time as PIC on such airships and up to a maximum of 5 hours.';
- (22) in Subpart C, Sections 5 and 6 are deleted;
- (23) point FCL.600 is replaced by the following:

## 'FCL.600 IR – General

Except as provided in point FCL.835, operations under IFR on an aeroplane, helicopter, airship or powered-lift aircraft shall be conducted only by holders of a PPL, CPL, MPL and ATPL with an IR appropriate to the category of aircraft or, if an IR appropriate to the category of aircraft is not available, only while undergoing skill testing or dual instruction.';

- (24) in point FCL.620, the following point (c) is added:
  - '(c) Applicants who have completed a skill test for a multi-engine IR in a single-pilot multi-engine aeroplane for which a class rating is required shall also be issued with a single-engine IR for the single-engine aeroplane class or type ratings that they hold.';
- (25) in point FCL.700, paragraph (a) is replaced by the following:
  - '(a) Holders of a pilot licence shall act as pilots of an aircraft only if they have a valid and appropriate class or type rating, unless any of the following applies:
    - (1) if exercising the privileges of an LAPL;
    - (2) if they take skill tests or proficiency checks for renewal of class or type ratings;
    - (3) if they receive flight instruction;
    - (4) if they hold a flight test rating issued in accordance with point FCL.820.';
- (26) in point FCL.725, the following paragraph (f) is added:
  - (f) Applicants for a class rating for TMGs who also hold an SPL in accordance with Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, including the privileges to fly on TMGs, shall receive full credits towards the requirements in paragraphs (a), (b) and (c).;
- (27) point FCL.740.A is amended as follows:
  - (a) paragraph (a)(4) is replaced by the following:
    - '(4) The revalidation of a BIR or an IR(A), if held, may be combined with a proficiency check for the revalidation of a class or type rating.';
  - (b) paragraph (b)(1) is replaced by the following:
    - (1) Single-engine piston aeroplane class ratings and TMG class ratings. For the revalidation of single-pilot singleengine piston aeroplane class ratings or TMG class ratings, the applicants shall.';
  - (c) the following paragraph (b)(5) is added:
    - (5) The proficiency check for the revalidation of a single-pilot single-engine aeroplane class rating may be combined with the proficiency check for the revalidation of a BIR, in accordance with point FCL.835(g)(8).';
- (28) point FCL.800 is amended as follows:
  - (a) paragraph (a) is replaced by the following:
    - (a) Holders of a pilot licence with privileges to fly aeroplanes or TMGs shall undertake aerobatic flights only if they hold an aerobatic rating in accordance with this point.';
  - (b) paragraph (b)(1) is replaced by the following:
    - (1) after the issue of the licence, at least 30 hours of flight time as PIC in aeroplanes or TMGs;';

- (c) paragraph (b)(2)(ii) is replaced by the following:
  - (ii) at least 5 hours of aerobatic instruction in aeroplanes or TMGs flown with engine power.';
- (d) paragraph (c) is replaced by the following:
  - '(c) The privileges of the aerobatic rating shall be limited to aerobatic flight in either aeroplanes or TMGs flown with engine power, depending on which aircraft the requirements of (b)(1) and (b)(2)(ii) were complied with. This limitation shall be lifted upon application if a pilot has successfully completed at least 3 dual training flights in aeroplanes or TMGs flown with engine power, as applicable, covering the full aerobatic training syllabus.';
- (e) the following paragraph (d) is added:
  - '(d) Applicants for an aerobatic rating who also hold a TMG class rating as well as advanced aerobatic privileges for sailplanes with privileges as specified in point SFCL.200(d) of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976 shall:
    - be exempted from getting their aerobatic rating limited to aeroplanes, as specified in paragraph (c) if they have complied with the requirements of (b)(1) and (b)(2)(ii) in aeroplanes, or
    - (2) receive full credit towards the requirements in paragraph (b) for the issue of an aerobatic rating restricted to TMGs flown with engine power. This limitation shall be lifted upon application if a pilot has completed the training as specified in paragraph (c).';
- (29) point FCL.805 is amended as follows:
  - (a) paragraph (b)(2)(iii) is replaced by the following:
    - '(iii) except for holders of an SPL in accordance with Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, 5 familiarisation flights in a sailplane which is launched by an aircraft.';
  - (b) the following paragraph (g) is added:
    - '(g) Applicants for a sailplane towing or banner towing rating on TMGs in accordance with this point shall receive full credit towards the requirements of paragraph (b) or (c), as applicable, if they hold a sailplane towing or banner towing rating in accordance with point SFCL.205 of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable, or if they have fulfilled all the requirements for the issue of that rating.';
- (30) point FCL.810 is amended as follows:
  - (a) paragraph (a) is amended as follows:
  - (i) paragraph (1) is replaced by the following:
    - '(1) Applicants shall have completed a training course within a period of up to 6 months at a DTO or at an ATO to exercise the privileges of an LAPL or a PPL for aeroplanes, TMGs or airships in VFR conditions at night.. The course shall comprise:';
  - (ii) the following paragraph(4) is added:
    - '(4) Applicants for a night rating for aeroplanes or TMGs in accordance with this subparagraph shall receive full credit towards the requirements of subparagraphs (1) and (2) if they hold a TMG night rating in accordance with point SFCL.210 of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976 or if they have fulfilled all the requirements for the issue of that rating.';
  - (b) paragraph (c) is deleted;
- (31) in point FCL.815, the introductory sentence of paragraph (a) is replaced by the following:
  - '(a) Privileges. The privileges of the holder of a mountain rating are to conduct flights with aeroplanes or TMGs to and from surfaces which are designated to require such a rating by the appropriate authorities designated by the Member States..

Holders of an LAPL or a PPL with privileges to fly aeroplanes or TMGs may obtain the initial mountain rating either on:';

- (32) point FCL.825 is deleted;
- (33) point FCL.830 is deleted;

(34) the following point FCL.835 is inserted:

## 'FCL.835 Basic instrument rating (BIR)

- (a) Privileges and conditions
  - (1) The privileges of a BIR holder are to conduct flights under IFR on single-pilot aeroplanes for which class ratings are held, with the exception of high-performance aeroplanes and aeroplane variants if operational suitability data has determined that an IR is required.
  - (2) BIR privileges shall only be exercised in accordance with point FCL.205.A.
  - (3) BIR privileges may be exercised at night only if the pilot holds a night rating in accordance with point FCL.810.
  - (4) The privileges of a multi-engine BIR shall also be valid on single-engine aeroplanes for which the pilot holds a valid single-engine class rating.
  - (5) The exercise of BIR privileges shall be subject to all of the following conditions:
    - (i) the decision height (DH) or minimum descent height (MDH) used in aerodrome operating minima shall be at least 200 ft greater than what would otherwise be calculated according to point 'NCO.OP.110 Aerodrome operating minima – aeroplanes and helicopters' and point 'NCO.OP.111 Aerodrome operating minima – NPA, APV, CAT I operations' to Annex VII of Regulation (EU) No 965/2012; and
    - (ii) the visibility used in aerodrome operating minima shall not be less than 1 500 m;
    - (iii) the pilot-in-command shall not commence a flight under IFR or undertake a VFR-to-IFR transition, unless:
      - (A) at the aerodrome of departure, the visibility is at least 1 500 m and the cloud ceiling is at least 600 ft, or the published circling minimum applicable to the aeroplane category, whichever is the greater; and
      - (B) at the destination aerodrome and at any required alternate aerodrome the available current meteorological information indicates, for the period from 1 hour before until 1 hour after the estimated time of arrival, or from the actual time of departure to 1 hour after the estimated time of arrival, whichever period is shorter, a visibility of at least 1 500 m and a cloud ceiling of at least 600 ft, or the published circling minimum applicable to the aeroplane category, or the DH/MDH incremented by 200 ft in accordance with (i), whichever is the greater.
- (b) Prerequisites. Applicants for the BIR shall hold at least a PPL(A).
- (c) Training course. Applicants for the BIR shall have completed at an ATO:
  - (1) theoretical knowledge instruction in accordance with point FCL.615(a); and
  - (2) flight instruction that comprises the following instrument flight instruction modules:
    - (i) module 1 the core flying training module of flight handling skills by sole reference to instruments;
    - (ii) module 2 the applied flying training module of IFR departure, holding, 2D and 3D approach procedures;
    - (iii) module 3 the applied flying training module of en-route IFR flight procedures; and
    - (iv) module 4 if a multi-engine BIR is sought, the applied flying training module with one engine inoperative shall include asymmetric instrument approach and go-around procedures; and
  - (3) flight instruction that complies with the following requirements:
    - (i) The module specified in paragraph (c)(2)(i) shall be completed first. The modules specified in paragraphs (c)(2)(ii) and (c)(2)(iii), and, if applicable, (c)(2)(iv), may be completed in an order chosen by the applicant.
    - (ii) The modules specified in paragraph (c)(2) may be completed in aeroplanes, FSTDs or a combination of these. In any case, the applicant shall receive training in the aeroplane to be used for the skill test.

- (iii) The modules specified in paragraphs (c)(2)(i), (c)(2)(ii) and (c)(2)(iv) may be commenced outside an ATO but shall be completed at an ATO. The module specified in point (c)(2)(iii) may be completed outside an ATO.
- (iv) Prior to commencing the module specified in paragraph (c)(2)(iv), a pilot who does not hold a multiengine aeroplane class or type rating shall have received the multi-engine training specified in Subpart H of this Annex (Part-FCL).
- (d) Theoretical knowledge. Prior to taking the skill test and through examinations in the subjects referred to in point FCL.615(b), the applicants shall demonstrate a level of theoretical knowledge that is appropriate to the privileges granted. The theoretical knowledge examination shall consist of one examination paper associated with each module as specified in paragraphs (c)(2)(i), (c)(2)(ii) and (c)(2)(ii).
- (e) Skill test. After the completion of the training course specified in paragraph (c), the applicants shall pass a skill test in an aeroplane in accordance with Appendix 7 to this Annex. For a multi-engine BIR, the skill test shall be taken in a multi-engine aeroplane. For a single-engine BIR, the skill test shall be taken in a single-engine aeroplane. A multi-engine centreline thrust aeroplane shall be considered to be a single-engine aeroplane for the purposes of this paragraph.
- (f) By way of derogation from paragraph (d), holders of a single-engine BIR who also hold a multi-engine class rating and who wish to obtain a multi-engine BIR for the first time shall complete a training course at an ATO that comprises the training as specified in paragraph (c)(2)(iv) and shall pass the skill test referred to in paragraph (e).
- (g) Validity, revalidation and renewal
  - (1) A BIR shall be valid for 1 year.
  - (2) Applicants for the revalidation of a BIR shall:
    - (i) within a period of three months immediately preceding the expiry date of the rating, pass a proficiency check in accordance with Appendix 9 to this Part; or
    - (ii) within the validity period, complete 6 hours as PIC under IFR including three instrument approach procedures and complete a training flight of at least one hour with an instructor who holds privileges to provide training for the BIR.
  - (3) For each alternate subsequent revalidation, the holder of the BIR shall pass a proficiency check in accordance with paragraph (2)(i) in an aeroplane.
  - (4) If a pilot chooses to fulfil the revalidation requirements specified in paragraph (g)(2)(i) earlier than what is prescribed in that paragraph, the new validity period shall commence from the date of the proficiency check.
  - (5) Applicants who fail to pass the relevant sections of a BIR proficiency check before the expiry date of the BIR shall not exercise the BIR privileges until they have passed the proficiency check.
  - (6) If a BIR has expired, in order to renew their privileges, applicants shall:
    - where necessary to reach the level of proficiency needed, complete refresher training provided by an ATO
      or, if the BIR is expired for three years or less, by an instructor who holds privileges to provide training
      for the BIR; and
    - (ii) pass a proficiency check in an aeroplane.
  - (7) For a multi-engine BIR, the proficiency check for the revalidation or renewal as well as the flying training required in paragraph (g)(2)(ii) shall be completed in a multi-engine aeroplane.
  - (8) The proficiency check for the revalidation or renewal of a BIR may be combined with a proficiency check for the revalidation or renewal of a single-pilot aeroplane class rating on which BIR privileges may be exercised in accordance with point FCL.835(a)(1).
- (h) Applicants for the BIR who hold a PPL or CPL issued in accordance with Annex I (Part-FCL) and a valid IR(A) issued in accordance with the requirements of Annex 1 to the Chicago Convention by a third country may be credited in full towards the training course referred to in paragraph (c)(2). In order to be issued with the BIR, the applicants shall:
  - (1) successfully complete the skill test referred to in paragraph (e);

- (2) demonstrate orally to the examiner during the skill test that they have acquired an adequate level of theoretical knowledge of air law, meteorology, and flight planning and performance; and
- (3) have experience of at least 25 hours of flight time under IFR as PIC on aeroplanes.
- (j) The holder of an IR shall receive full credits for the requirement in paragraph (c)(2).';
- (35) point FCL.915(c)(1) is replaced by the following:
  - (c) Credit towards further instructor certificates and for the purpose of revalidation:
    - (1) Full credit towards the teaching and learning skills may be granted to:
      - (i) holders of an instructor certificate who apply for further instructor certificates; and
      - (ii) applicants for an instructor certificate who already hold an instructor certificate issued in accordance with Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 or with Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.';
- (36) point FCL.905.FI is amended as follows:
  - (a) paragraph (a) is replaced by the following:
    - '(a) a PPL and LAPL in the appropriate aircraft category;';
  - (b) paragraph (b) is replaced by the following:
    - (b) class and type ratings for single-pilot aircraft, except for single-pilot high-performance complex aeroplanes;';
  - (c) paragraph (g) is replaced by the following:
    - '(g) a towing or aerobatic rating, provided that such privileges are held and the FI has demonstrated the ability to instruct for that rating to an FI who is qualified in accordance with point (j);';
  - (d) paragraph (h) is replaced by the following:
    - (h) a BIR or an IR in the appropriate aircraft category, provided that FI meets the following conditions:
      - (1) they have completed as student pilots the IRI training course and have passed an assessment of competence for the IRI certificate;
      - (2) they comply with points FCL.915.CRI(a), FCL.930.CRI and FCL.935 in the case of multi-engine aeroplanes and with points FCL.910.TRI(c)(1) and FCL.915.TRI(d)(2) in the case of multi-engine helicopters;

In addition to conditions (1) and (2):

- (3) if during an approved training course at an ATO, the FI is providing training in FSTDs or supervising SPIC training flights that take place under IFR, the FI shall have completed at least 50 hours of flight time under IFR after the issuance of the BIR or the IR, of which a maximum of 10 hours may be instrument ground time in an FFS, an FTD 2/3 or an FNPT II,;
- (4) if the FI is providing training in an aircraft, the FI shall have completed at least 200 hours of flight time under IFR, of which up to 50 hours may be instrument ground time in an FFS, an FTD 2/3 or an FNPT II.'
- (e) paragraph (j)(1) is replaced by the following:
  - (1) they have completed at least 500 hours of flight instruction in the appropriate aircraft category;";
- (37) point FCL.910.FI is amended as follows:
  - (a) paragraph (a) is amended as follows:
  - (i) point (1) is replaced by the following:
    - '(1) for the issue of the PPL and LAPL;';

- (ii) point (3) is replaced by the following:
  - '(3) for class and type ratings for single-pilot, single-engine aircraft, except for single-pilot high-performance complex aeroplanes;';
- (b) in paragraph (c), point (3) is replaced by the following:
  - '(3) for the FI(As), 15 hours or 50 take-offs of flight instruction covering the full training syllabus for the issue of a PPL(As).';
- (38) in point FCL.915.FI, paragraphs (e) and (f) are deleted;
- (39) paragraph (b) of point FCL.930.FI is amended as follows:
  - (a) paragraph (2) is replaced by the following:
    - (2) at least 100 hours of theoretical knowledge instruction, including progress tests;';
  - (b) in paragraph (3):
  - (i) point (ii) is replaced by the following:
    - '(ii) in the case of an FI(As), at least 20 hours of flight instruction, of which 15 hours shall be dual flight instruction.';
  - (ii) points (iii), (iv) and (v) are deleted;
  - (c) paragraph (4) is replaced by the following:
    - '(4) Applicants for an FI certificate in another category of aircraft who are holding or have held an FI(A), (H) or (As) shall be credited with 55 hours towards the requirement in point (b)(2).';
- (40) paragraph (a) of point FCL.940.FI is amended as follows:
  - (a) paragraph (1)(i)(A) is replaced by the following:
    - '(A) in the case of an FI(A) and an FI(H), at least 50 hours of flight instruction in the appropriate aircraft category as FIs, TRIs, CRIs, IRIs MIs or examiners. If the privileges to instruct for the BIR and the IR are to be revalidated, 10 of those 50 hours shall be flight instruction for a BIR or an IR and shall have been completed within the last 12 months immediately preceding the expiry date of the FI certificate;';
  - (b) paragraphs (1)(i)(C) and (1)(i)(D) are deleted;
  - (c) paragraph (2) is replaced by the following:
    - '(2) For at least each alternate revalidation, in the case of FI(A) or FI(H), or each third revalidation, in the case of FI (As), holders of the relevant FI certificate shall pass an assessment of competence in accordance with point FCL.935.';
- (41) in point FCL.905.TRI, paragraph (a) is replaced by the following:
  - '(a) the revalidation and renewal of an IR, provided the TRI holds a valid IR;';
- (42) in point FCL.905.IRI, paragraph (a) is replaced by the following:
  - '(a) The privileges of IRIs are to instruct for the issue, revalidation and renewal of a BIR and an IR in the appropriate aircraft category.';
- (43) point FCL.915.IRI is replaced by the following:

## FCL.915.IRI

Applicants for an IRI certificate shall:

- (a) in case of an IRI(A):
  - (1) to provide training in FSTDs during an approved training course at an ATO, have completed at least 200 hours of flight time under IFR after the issuance of the BIR or the IR, of which at least 50 hours shall be in aeroplanes;

- (2) to provide training in an aeroplane, have completed at least 800 hours of flight time under IFR, of which at least 400 hours shall be in aeroplanes;
- (3) to apply for an IRI(A) for multi-engine aeroplanes, meet the requirements of points FCL.915.CRI(a), FCL.930. CRI and FCL.935;
- (b) for an IRI(H):
  - to provide training in FSTDs during an approved training course at an ATO, have completed at least 125 hours of flight time under IFR after the issuance of the IR, of which at least 65 hours shall be instrument flight time in helicopters;
  - (2) to provide training in a helicopter, have completed at least 500 hours of flight time under IFR, of which at least 250 hours shall be instrument flight time in helicopters; and
  - (3) to apply for an IR(H) for multi-engine helicopters, meet the requirements of point FCL.905.FI(h)(2);
- (c) Applicants for an IRI(As) certificate shall have completed at least 300 hours of flight time under IFR, of which at least 100 hours shall be instrument flight time in airships.';
- (44) in point FCL.905.STI, paragraph (a)(2) is replaced by the following:
  - (2) the issue, revalidation or renewal of a BIR and an IR and a class or type rating for single-pilot aircraft, except for single-pilot high-performance complex aeroplanes.';
- (45) in point FCL.1005.FE, paragraphs (d) and (e) are deleted.
- (46) in point FCL.1005.TRE, paragraph (a)(2) is replaced by the following:
  - (2) proficiency checks for the revalidation or renewal of type ratings and IRs;';
- (47) in point FCL.1005.CRE, paragraph (b)(4) is replaced by the following:
  - '(4) revalidation and renewal of BIRs, provided that the CRE has completed:
    - (i) 1 500 hours of flight time as a pilot of aeroplanes; and
    - (ii) 450 hours of flight time under IFR; and';
- (48) point FCL.1005.IRE is replaced by the following:

## 'FCL.1005.IRE IRE – Privileges

The privileges of holders of an instrument rating examiner (IRE) certificate are to conduct skill tests for the issue and proficiency checks for the revalidation or renewal of BIRs and IRs.';

- (49) in point FCL.1010.SFE, paragraphs (a) (1) and (2) are amended as follows:
  - '(a) SFE(A)

Applicants for an SFE(A) certificate shall comply with all of the following conditions:

- (1) in the case of multi-pilot aeroplanes:
  - (i) hold or have held an ATPL(A) and a type rating;
  - (ii) an SFI(A) certificate for the applicable type of aeroplane; and
  - (iii) have at least 1500 hours of flight time as pilots of multi-pilot aeroplanes;
- (2) in the case of single-pilot high-performance complex aeroplanes:
  - (i) hold or have held a CPL(A) or an ATPL(A) and a type rating;
  - (ii) an SFI(A) certificate for the applicable class or type of aeroplane; and
  - (iii) have at least 500 hours of flight time as pilots of single-pilot aeroplanes;'

- (50) in point FCL.1005.FIE, paragraph (c) is amended as follows:
  - (c) FIE(As). The privileges of an FIE on airships are to conduct assessments of competence for the issue, revalidation or renewal of instructor certificates of airships, provided that the relevant instructor certificate is held.';
- (51) in point FCL.1010.FIE, paragraphs (d) and (e) are deleted;
- (52) Appendix 1 is amended as follows:
  - (a) point 1 is replaced by the following:

## '1. LAPL and PPL';

- (b) paragraphs 1.1. and 1.2. are replaced by the following:
  - '1.1. For the issue of an LAPL, the holder of an LAPL in another category of aircraft shall be fully credited towards requirements of theoretical knowledge on the common subjects established in point FCL.120(a).
  - 1.2. For the issue of an LAPL or a PPL, holders of a PPL, CPL or ATPL in another category of aircraft shall be credited towards requirements of theoretical knowledge on the common subjects established in point FCL.215(a). This credit shall also apply to applicants for an LAPL or a PPL who hold a BPL issued in accordance with Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 or an SPL issued in accordance with Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, except that the subject 'navigation' shall not be credited.';
- (c) paragraph 1.2a. is deleted;
- (d) paragraph 1.3 is replaced by the following:
  - '1.3. For the issue of a PPL, the holder of an LAPL in the same category of aircraft shall be fully credited towards the requirements of theoretical knowledge instruction and examination.';
- (e) paragraph 1.4 is replaced by the following:
  - '1.4. By way of derogation from paragraph 1.2, for the issue of an LAPL(A), the holder of an SPL issued in accordance with Annex III (Part-SFCL) to Implementing Regulation (EU) 2018/1976 with privileges to fly TMGs shall demonstrate an adequate level of theoretical knowledge for the single-engine piston aeroplane-land class in accordance with point FCL.135.A(a)(2).';
- (f) paragraph 4.1 is replaced by the following:
  - '4.1. Applicants for an IR, or for a BIR, who have passed the relevant theoretical examinations for a CPL in the same aircraft category, shall be credited towards the theoretical knowledge requirements in the following subjects:
    - Human Performance,
    - Meteorology.';
- (53) Appendix 3 is amended as follows:
  - (a) in Chapter A, the paragraph following point 9(f)(3)(ii) is replaced by the following:

'Applicants holding a BIR or a course completion certificate for the Basic Instrument Flight Module shall be credited with up to 10 hours towards the required instrument instruction time. Hours done in a BITD shall not be credited.';

(b) in Chapter C, the paragraph following point 8(e)(2)(ii) is replaced by the following:

'Applicants holding a BIR or a course completion certificate for the Basic Instrument Flight Module shall be credited with up to 10 hours towards the required instrument instruction time. Hours done in a BITD shall not be credited; and';

- (c) in Chapter D, point 8(e) is replaced by the following:
  - (e) 10 hours of instrument flight instruction, of which up to 5 hours may be instrument ground time in an FNPT I, FTD 2, FNPT II or FFS. Applicants holding a BIR or a course completion certificate for the Basic Instrument Flight Module shall be credited with up to 10 hours towards the required instrument instruction time. Hours done in a BITD shall not be credited;';

- (d) in Chapter E, point (a) in point 3 is replaced by the following:
  - '(a) have completed 150 hours flight time; including 50 hours as PIC on aeroplanes of which 10 hours shall be cross-country.

Except for the requirement of 50 hours as PIC in aeroplanes, hours as PIC in other categories of aircraft may account for the 150 hours of aeroplane flight time in any of the following cases:

- (1) 20 hours in helicopters, if applicants hold a PPL(H);
- (2) 50 hours in helicopters, if applicants hold a CPL(H);
- (3) 10 hours in TMGs or sailplanes;
- (4) 20 hours in airships, if applicants hold a PPL(As);
- (5) 50 hours in airships, if applicants hold a CPL(As).';
- (e) in Chapter E, point 9 is replaced by the following:
  - '9. Applicants holding a valid IR(A) shall be credited towards the dual instrument instruction time. Applicants holding a valid IR(H) shall be credited up to 5 hours of the dual instrument instruction time, in which case at least 5 hours dual instrument instruction time shall be given in an aeroplane. Applicants holding a BIR or a Course Completion Certificate for the Basic Instrument Flight Module shall be credited with up to 10 hours towards the required instrument instruction time.';
- (f) in Chapter E, point 12(c) is replaced by the following:
  - '(c) 10 hours of instrument flight instruction, of which up to 5 hours may be instrument ground time in an FNPT I, or FNPT II or FFS. Applicants holding a BIR or a course completion certificate for the Basic Instrument Flight Module shall be credited with up to 10 hours towards the required instrument instruction time. Hours done in a BITD shall not be credited;';
- (54) in Appendix 6, Chapter A is amended as follows:
  - (a) 'paragraph 2 is replaced by the following:
    - '2. Applicants for a modular IR(A) course shall be the holder of a PPL(A) or a CPL(A). Applicants for the Procedural Instrument Flight Module, who does not hold a CPL(A), shall be a holder of a BIR or of a Course Completion Certificate for the Basic Instrument Flight Module.';
  - (b) paragraph 10.1 is replaced by the following:
    - '10.1. Holders of a CPL(A), of a BIR, or of a Course Completion Certificate for the Basic Instrument Flight Module shall be credited with up to 10 hours in regard of the total amount of training required in paragraphs 7 or 8 above';
- (55) in Appendix 6, Chapter Aa is amended as follows:
  - (a) paragraphs 9 and 10 are renumbered to 11 and 12;
  - (b) paragraphs 9 and 10 are inserted as follows:
  - '9. Applicants for the competency-based modular IR(A) who hold a BIR in accordance with point FCL.835 and who have received at least 10 hours of instrument flight time under instruction at an ATO may be credited towards the training course referred to in paragraph 4, provided that all competency-based instrument rating topics have been included in that BIR training, and assessed by the ATO that provides the competency-based modular flying training course.
  - 10. Applicants for the competency-based modular IR(A) who hold a BIR and have experience of at least 50 hours of flight time under IFR as PIC on aeroplanes, shall:
    - (a) at an ATO:
      - (i) be assessed as having an acceptable standard of competency-based instrument rating theoretical knowledge;
      - (ii) receive appropriate flight training to extend IFR privileges in accordance with FCL.605.IR(a);

- (b) after completion of (a);
  - (i) successfully complete the skill test for the IR(A) in accordance with Appendix 7;
  - (ii) demonstrate orally to the examiner during the skill test that they have acquired an adequate level of theoretical knowledge of air law, meteorology, and flight planning and performance.';
- (56) Appendix 7 is amended as follows:
  - (a) the title is replaced by 'BIR and IR skill test';
  - (b) paragraph 1 is replaced by the following:
    - Applicants shall have received instruction on the same class or type of aircraft to be used in the test which shall be appropriately equipped for the training and testing purposes.';
  - (c) paragraph 9 is replaced by the following:
    - '9. Applicants shall indicate to the examiner the checks and duties carried out, including the identification of radio facilities. Checks shall be completed in accordance with the authorised checklist for the aircraft on which the test is being taken. During pre-flight preparation for the test applicants shall determine power settings and speeds. The applicants shall calculate performance data for take-off, approach and landing in compliance with the operations manual or flight manual for the aircraft used.';
  - (d) in paragraph 11, at the end of the table for 'aeroplanes', the text for the footnote (++) is replaced by the following:
    - '(++) To establish PBN privileges, one approach in either Section 4 or Section 5 shall be an RNP APCH. Where an RNP APCH is not practicable, it shall be performed in an appropriately equipped FSTD.';
  - (e) in paragraph 11, at the end of the table for "helicopters", the text for the footnote (+) is replaced by the following:
    - (+) To establish PBN privileges, one approach in either Section 4 or Section 5 shall be an RNP APCH. Where an RNP APCH is not practicable, it shall be performed in an appropriately equipped FSTD.';
- (57) the title of Appendix 9 replaced by 'Training, skill test and proficiency check for MPL, ATPL, type and class ratings, and proficiency check for the BIR and IR'.
- (58) Appendix 9 is amended as follows:
  - (a) in point 5 of Section B, point (l) is replaced by the following:
    - (l) To establish or maintain PBN privileges, one approach shall be an RNP APCH. Where an RNP APCH is not practicable, it shall be performed in an appropriately equipped FSTD.

By way of derogation from the subparagraph above, in cases where a proficiency check for revalidation of PBN privileges does not include an RNP APCH exercise, the PBN privileges of the pilot shall not include RNP APCH. The restriction shall be lifted if the pilot has completed a proficiency check including an RNP APCH exercise.';

- (b) in point 6 of Section B, point (d) is replaced by the following:
  - '(d) Where the letter 'M' appears in the skill test or proficiency check column, this will indicate a mandatory exercise or a choice where more than one exercise appears.';
- (c) in point 6 of point (B), point (j) is replaced by the following:
  - (j) To establish or maintain PBN privileges, one approach shall be an RNP APCH. Where an RNP APCH is not practicable, it shall be performed in an appropriately equipped FSTD.

By way of derogation from the subparagraph above, in cases where a proficiency check for revalidation of PBN privileges does not include an RNP APCH exercise, the PBN privileges of the pilot shall not include RNP APCH. The restriction shall be lifted if the pilot has completed a proficiency check including an RNP APCH exercise.';

'3.8.3.4*	Manually, with one engine simu-				
'3.8.3.4*	<ul> <li>Manually, with one engine simulated inoperative during final approach, either until touchdown or through the complete missed approach procedure (as applicable), starting:</li> <li>(i) before passing 1 000 ft above aerodrome level; and</li> <li>(ii) after passing 1 000 ft above aerodrome level.</li> <li>In aeroplanes which are not certificated as transport category aero-</li> </ul>				
	planes (JAR/FAR 25) or as commu- ter category aeroplanes (SFAR 23), the approach with simulated en- gine failure and the ensuing go- around shall be initiated in con- junction with the 2D approach in accordance with 3.8.4. The go- around shall be initiated when	P>	>	M'	
	reaching the published obstacle clearance height/altitude (OCH/A); however, not later than reaching an MDH/A of 500 ft above the run- way threshold elevation. In aero- planes having the same perfor- mance as a transport category				
	aeroplane regarding take-off mass and density altitude, the instructor may simulate the engine failure in accordance with exercise 3.8.3.4.				

(d) in point 6 of Section B, in the table following point (j), the row for exercise 3.8.3.4 is replaced by the following:

- (e) in point 6 of Section B, in the table following point (j), the row for exercise 3.8.3.5 is deleted.
- (f) in Section C, a new point 8a is inserted as follows:
  - (8a) To establish or maintain PBN privileges, one approach shall be an RNP APCH. Where an RNP APCH is not practicable, it shall be performed in an appropriately equipped FSTD.

By way of derogation from subparagraph above, in cases where a proficiency check for revalidation of PBN privileges does not include an RNP APCH exercise, the PBN privileges of the pilot shall not include RNP APCH. The restriction shall be lifted if the pilot has completed a proficiency check including an RNP APCH exercise.'

## 5.3.2020

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## ANNEX II

Point MED.A.030 of Annex IV (Part-MED) to Commission Regulation (EU) No 1178/2011 is amended as follows:

- (a) paragraph (c) is replaced by the following:
  - '(c) When exercising the privileges of a:
    - light aircraft pilot licence (LAPL), a balloon pilot licence (BPL) issued in accordance with Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395, or a sailplane pilot licence (SPL) issued in accordance with Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, the pilot shall hold at least a valid LAPL medical certificate;
    - (2) private pilot licence (PPL), the pilot shall hold at least a valid class 2 medical certificate;
    - (3) BPL for the purpose of:
      - (i) commercial passenger ballooning, the pilot shall hold at least a valid class 2 medical certificate;
      - (ii) commercial operation other than commercial passenger ballooning, with more than 4 persons on board the aircraft, the pilot shall hold at least a valid class 2 medical certificate;
    - (4) SPL for the purpose of commercial sailplane operations other than those specified in Article 3(2) of Commission Implementing Regulation (EU) 2018/1976, the pilot shall hold at least a valid class 2 medical certificate;
    - (5) a commercial pilot licence (CPL), a multi-crew pilot licence (MPL) or an airline transport pilot licence (ATPL), the pilot shall hold a valid class 1 medical certificate.';
- (b) paragraph (e) is replaced by the following:
  - (e) If an instrument rating or basic instrument rating is added to a PPL, the licence holder shall undergo pure tone audiometry examinations in accordance with the periodicity and the standard required for class 1 medical certificate holders.'

#### ANNEX III

Annex VI (Part-ARA) to Commission Regulation (EU) No 1178/2011 is amended as follows:

- (1) in point ARA.GEN.220, paragraph (b) is replaced by the following:
  - (b) The competent authority shall establish and keep up to date a list of all organisation certificates, FSTD qualification certificates and personnel licences, certificates and attestations it issued, DTO declarations it received, and the DTO training programmes it verified or approved for compliance with Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395, or Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.';
- (2) point ARA.GEN.350 is amended as follows:
  - (a) the introductory sentence of paragraph (da) is replaced by the following:
    - '(da) By way of derogation from paragraphs (a) to (d), in the case of DTOs, if during oversight or by any other means the competent authority finds evidence that indicates DTO non-compliance with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139, with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation, or with the requirements of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, the competent authority shall:';
  - (b) paragraph (e) is replaced by the following:
    - '(e) Without prejudice to any additional enforcement measures, if the authority of a Member State that acts in accordance with point ARA.GEN.300(d) identifies any non-compliance with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139, with the requirements of Annex I (Part-FCL), Annex VII (Part-ORA) and Annex VIII (Part-DTO) to this Regulation, or with the requirements of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976 by an organisation certified by, or having made a declaration to, the competent authority of another Member State or the Agency, it shall inform that competent authority of that non-compliance.';
- (3) in point ARA.GEN.360, point (a) is replaced by the following:
  - '(a) Upon receiving a licence holder's request for a change of competent authority as specified in point FCL.015(e) of Annex I (Part-FCL), point BFCL.015(f) of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 or point SFCL.015(f) of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, the receiving competent authority shall, without undue delay, request the competent authority of the licence holder to transfer, without undue delay, all of the following:
    - (1) a verification of the licence;
    - (2) copies of the licence holder's medical records kept by that competent authority in accordance with points ARA.GEN.220 and ARA.MED.150. The medical records shall be transferred in accordance with point MED.A.015 of Annex IV (Part-MED) and shall include a summary of the relevant medical history of the applicant, verified and signed by the medical assessor.';
- (4) in point ARA.FCL.200, the following paragraph (e) is added:
  - (e) Instructors for FI(B) or FI(S) certificates: The competent authority shall develop appropriate procedures for the conduct of the training flights under supervision specified in:
    - (1) points BFCL.315(a)(5)(ii) and BFCL.360(a)(2) of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395; and
    - (2) points SFCL.315(a)(7)(ii) and SFCL.360(a)(2) of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.';
- (5) in point ARA.FCL.250(a), subparagraph (3) is replaced by the following:
  - '(3) the licence holder no longer complies with the applicable requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 or Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976;';

- (6) in point ARA.FCL.300, paragraph (a) is replaced by the following:
  - '(a) The competent authority shall put in place the necessary arrangements and procedures to allow applicants to take theoretical knowledge examinations in accordance with the applicable requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 or Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.';
- (7) the following point ARA.ATO.110 is inserted after point ARA.ATO.105:

#### 'ARA.ATO.110 Approval of minimum equipment lists

When the competent authority receives an application for approval of a minimum equipment list under points ORO. MLR.105 of Annex III (Part-ORO) and NCC.GEN.101 of Annex VI (Part-NCC) to Regulation (EU) No 965/2012, it shall act in accordance with point ARO.OPS.205 of Annex II (Part-ARO) to that Regulation.';

- (8) in point ARA.DTO.100, paragraph (b) is replaced by the following:
  - '(b) If the declaration does not contain the required information or contains information that indicates a noncompliance with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139, with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation, or with the requirements of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, the competent authority shall act in accordance with point ARA. GEN.350(da).';
- (9) in point ARA.DTO.110, paragraph (a) is replaced by the following:
  - '(a) Upon receiving the training programmes of a DTO, and any changes thereto, notified to it in accordance with point DTO.GEN.115(c) of Annex VIII (Part-DTO) or the application for approval of the training programmes of a DTO submitted to it in accordance with point DTO.GEN.230(c) of that Annex, the competent authority shall verify the compliance of those training programmes with the requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable.';
- (10) Appendix I is amended as follows:
  - (a) the introductory sentence after the heading 'Flight crew licence' is replaced by the following:

'The flight crew licence issued by a Member State in accordance with Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976 shall conform to the following specifications:';

- (b) paragraph (a)(1)(III) is replaced by the following:
  - '(III) serial number of the licence commencing with the UN country code of the State of licence issue and followed by 'FCL', 'BFCL' or 'SFCL', as applicable, and a code of numbers and/or letters in Arabic numerals and in Latin script;';
- (c) paragraph (a)(2)(XII) is replaced by the following:
  - '(XII) ratings, certificates and, in the case of balloons and sailplanes, privileges: class, type, instructor certificates, etc., with dates of expiry, as applicable. Radio telephony (R/T) privileges may appear on the licence or on a separate certificate;';
- (d) the template following paragraph (c), with the heading 'Cover page' (EASA Form 141 Issue 2), is amended as follows:
  - (i) the phrase 'Issued in accordance with Part-FCL' is replaced by the following:

'Issued in accordance with Part-FCL/Part-BFCL/Part-SFCL (non-applicable terms to be deleted)';

(ii) the phrase 'This licence complies with ICAO standards, except for the LAPL and EIR privileges' is replaced by the following:

'This licence complies with ICAO standards, except for the LAPL and BIR privileges or when accompanied by an LAPL medical certificate';

(e) in the template following the heading 'Page 2', the phrase 'Serial number of the licence will always commence with the UN country code of the State of the licence issue, followed by 'FCL.' (remark associated with field No III – Licence number) is replaced by the following:

'Serial number of the licence will always commence with the UN country code of the State of the licence issue, followed by "FCL.", "BFCL." or "SFCL.", as applicable.';

- (f) the template following the heading 'Page 3' is amended as follows:
  - (i) the phrase 'Abbreviations used will be as used in Part-FCL (e.g. PPL(H), ATPL(A), etc.)' (text associated with field No II Title of the licence, date of initial issue and country code) is replaced by the following:

'Abbreviations used will be as those used in Part-FCL (e.g. PPL(H), ATPL(A), etc.), Part-BFCL and Part-SFCL';

(ii) after the phrase 'In case of LAPL: LAPL not issued in accordance with ICAO standards' (text associated with field No XIII – Remarks), the following text is added:

In case of SPL, except for the cases referred to in Point 2(b) of Article 3b of Commission Implementing Regulation (EU) 2018/1976: Privileges for aerobatic and sailplane cloud flying as well as for launching methods to be exercised in accordance with points SFCL.155, SFCL.200 and SFCL.215 of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable.'.

(11) Appendix III is replaced by the following:

#### 'CERTIFICATE FOR APPROVED TRAINING ORGANISATIONS (ATOs)

#### **European Union \***

**Competent Authority** 

### APPROVED TRAINING ORGANISATION CERTIFICATE

#### [CERTIFICATE NUMBER/REFERENCE]

Pursuant to Commission Regulation (EU) No 1178/2011 [and Commission Regulation (EU) 2018/395/Commission Implementing Regulation (EU) 2018/1976 (ADJUST AS APPLICABLE)] and subject to the conditions specified below, the [Competent Authority] hereby certifies

[NAME OF THE TRAINING ORGANISATION]

[ADDRESS OF THE TRAINING ORGANISATION]

as a Part-ORA certified training organisation with the privilege to provide Part-FCL training courses, including the use of FSTDs, as listed in the attached training course approval/Part-BFCL training courses/Part-SFCL training courses [ADJUST AS APPLICABLE].

### CONDITIONS:

This certificate is limited to the privileges and the scope of providing the training courses, including the use of FSTDs, as listed in the attached training course approval.

This certificate is valid whilst the approved organisation remains in compliance with Part-ORA, Part-FCL, Part-BFCL, Part-SFCL [ADJUST AS APPLICABLE] and other applicable regulations.

Subject to compliance with the foregoing conditions, this certificate shall remain valid unless it has been surrendered, superseded, limited, suspended or revoked.

Date of issue:

Signed:

[Competent Authority]

"European Union" to be deleted for non-EU Member States

EASA FORM 143 Issue 2 – Page 1/2

## APPROVED TRAINING ORGANISATION CERTIFICATE

### TRAINING COURSE APPROVAL

Attachment to ATO Certificate Number:

[CERTIFICATE NUMBER/REFERENCE]

[NAME OF THE TRAINING ORGANISATION]

has obtained the privilege to provide and conduct the following Part-FCL/Part-BFCL/Part-SFCL [ADJUST AS APPLICABLE] training courses and to use the following FSTDs:

Training course	FSTD(s) used, including letter code (1)		

(1) as indicated on the qualification certificate

This training course approval is valid as long as:

- (a) the ATO certificate has not been surrendered, superseded, limited, suspended or revoked; and
- (b) all operations are conducted in compliance with Part-ORA, Part-FCL, Part-BFCL, Part-SFCL [ADJUST AS APPLICABLE], other applicable regulations, and, when relevant, with the procedures in the organisation's documentation as required by Part-ORA.

Date of issue:

Signed: [Competent Authority]

For the Member State/EASA

EASA FORM 143 Issue 2 – Page 2/2';

(12) Appendix VIII is replaced by the following:

### 'Training programme approval

for a declared training organisation (DTO)

European Union (\*)

Competent authority

Issuing authority:	
Name of DTO:	
DTO reference number:	

Training programme(s) approved:	Doc reference:	Remarks:
Examiner standardisation – FE(S), FE(B) (**)	-	
Examiner refresher course – FE(S), FE(B) (**)		

The above-mentioned training programme(s) has (have) been verified by the above-mentioned competent authority and found to be in compliance with the requirements of Annex I (Part-FCL) to Commission Regulation (EU) No 1178/2011, Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.

Date of issue:

Signed: [competent authority]

(\*) "European Union" to be deleted for non-EU Member States.

(\*\*) To be adjusted as applicable.

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### ANNEX IV

Annex VII (Part-ORA) to Commission Regulation (EU) No 1178/2011 is amended as follows:

- (1) point ORA.ATO.110 is amended as follows:
  - (a) in paragraph (b), subparagraph (1) is replaced by the following:
    - '(1) ensuring that the training provided is in compliance with Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395, Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable, and, in the case of flight test training, that the relevant requirements of Annex I (Part 21) to Commission Regulation (EU) No 748/2012 and the training programme have been established;';
  - (b) paragraph (d) is replaced by the following:
    - '(d) Flight instructors and flight simulation training instructors shall hold the qualifications required by Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976 for the type of training they provide.';
- (2) in point ORA.ATO.125, paragraph (b) is replaced by the following:
  - '(b) The training programme shall comply with the requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395, Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable, and, in the case of flight test training, the relevant requirements of Annex I (Part 21) to Commission Regulation (EU) No 748/2012.'.

#### ANNEX V

Annex VIII (Part-DTO) to Commission Regulation (EU) No 1178/2011 is amended as follows:

- (1) point DTO.GEN.110 is amended as follows:
  - (a) paragraphs (a)(3) and (4) are replaced by the following:
    - (3) for sailplanes, in accordance with the requirements of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976:
      - (a) theoretical knowledge instruction for the SPL;
      - (b) flight instruction for the SPL;
      - (c) training towards extension of privileges to sailplanes or TMGs in accordance with point SFCL150;
      - (d) training towards additional launching methods in accordance with point SFCL.155;
      - (e) training towards additional ratings and privileges: basic aerobatic and advanced aerobatic privileges, sailplane and banner towing rating, TMG night rating, and sailplane cloud flying privileges;
      - (f) training towards flight instructor certificate for sailplanes (FI(S));
      - (g) FI(S) refresher course;
    - (4) for balloons, in accordance with the requirements of Annex III (Part-BFCL) to Commission Implementing Regulation (EU) 2018/1976:
      - (a) theoretical knowledge instruction for the BPL;
      - (b) flight instruction for the BPL;
      - (c) training towards class or group extension in accordance with point BFCL.150;
      - (d) training towards additional ratings: tethered hot-air balloon flight, night, and commercial operation rating;
      - (g) training towards flight instructor certificate for balloons (FI(B));
      - (h) FI(B) refresher course.';
  - (b) paragraph (b) is replaced by the following:
    - '(b) A DTO shall be entitled to also provide the examiner courses referred to in points BFCL.430 and BFCL.460(b) (1) of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 for FE(B), as well as in points SFCL.430 and SFCL.460(b)(1) of Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976 for FE (S), provided that the DTO has submitted a declaration in accordance with point DTO.GEN.115 and the competent authority has approved the training programme in accordance with point DTO.GEN.230(c).';
- (2) in point DTO.GEN.115(a), subparagraph (8) is replaced by the following:
  - '(8) a statement that confirms that the DTO complies and will, during all training activities covered by the declaration, continue to comply with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139, with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation and with the requirements of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976.';
- (3) point DTO.GEN.210 is amended as follows:
  - (a) paragraph (a)(2)(i) is replaced by the following:
    - '(i) that the training provided complies with the requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Regulation (EU) 2018/1976 and with the DTO's training programme;';

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- (b) paragraph (e) is replaced by the following:
  - (e) Flight instructors and flight simulation training instructors shall hold the qualifications required by Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976 for the type of training they provide.';
- (4) point DTO.GEN.230 is amended as follows:
  - (a) paragraph (b) is replaced by the following:
    - '(b) The training programmes shall comply with the requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable.';
  - (b) paragraph (c) is replaced by the following:
    - '(c) A DTO shall be entitled to provide the training referred to in point DTO.GEN.110(b) only when its training programme for that training, and any changes thereto, have been issued by the competent authority, upon application by the DTO, with an approval in accordance with point ARA.DTO.110, confirming that the training programme and any changes thereto comply with the requirements of Annex I (Part-FCL), Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976, as applicable. A DTO shall apply for such approval through the submission of its declaration in accordance with point DTO.GEN.115.';
- (5) in Appendix 1, Section 9 of the declaration form is replaced by the following:

# '9. Statement The DTO has developed a safety policy in accordance with Annex VIII (Part-DTO) to Commission Regulation (EU) No 1178/2011, and in particular with point DTO.GEN.210(a)(1)(ii) thereof, and will apply that policy during all training activities covered by the declaration. The DTO complies and will, during all training activities covered by the declaration, continue to comply with the essential requirements set out in Annex IV to Regulation (EU) 2018/1139, with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to Commission Regulation (EU) No 1178/2011, and with the requirements of Annex III (Part-BFCL) to Commission Regulation (EU) 2018/395 and Annex III (Part-SFCL) to Commission Implementing Regulation (EU) 2018/1976. We confirm that all information contained in this declaration, including its annexes (if applicable), is complete and correct. Name, date and signature of the representative of the DTO

# DIRECTIVES

#### COMMISSION DELEGATED DIRECTIVE (EU) 2020/360

#### of 17 December 2019

amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in platinized platinum electrodes used for certain conductivity measurements

#### (Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (<sup>1</sup>), and in particular Article 5(1)(a) thereof,

- (1) Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That restriction does not apply to certain exempted applications which are specific to medical devices and monitoring and control instruments and are listed in Annex IV to that Directive.
- (2) The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive.
- (3) Lead is a restricted substance listed in Annex II to Directive 2011/65/EU.
- (4) By Delegated Directive 2014/73/EU (<sup>2</sup>), the Commission granted an exemption for the use of lead in platinized platinum electrodes used for conductivity measurements where certain conditions apply ('the exemption'), by including the relevant applications in Annex IV to Directive 2011/65/EU. The exemption was to expire on 31 December 2018, in accordance with the third subparagraph of Article 5(2) of that Directive.
- (5) The Commission received an application for renewal of the exemption ('the renewal request') on 30 June 2017, that is within the time limit laid down in Article 5(5) of Directive 2011/65/EU. In accordance with that provision, the exemption remains valid until a decision on the renewal request has been adopted.
- (6) The evaluation of the renewal request included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.
- (7) Lead-containing platinized platinum electrodes are used in specialised instruments for measurements which require certain measurement qualities such as wide range, high accuracy, or high reliability for high concentration of acid and alkali.
- (8) Due to the lack of reliable alternatives, a substitution or elimination of lead in the applications concerned is currently scientifically and technically impracticable for certain measurement instruments. The renewal of the exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council (<sup>3</sup>) and thus does not weaken the environmental and health protection afforded by it.

<sup>(&</sup>lt;sup>1</sup>) OJ L 174, 1.7.2011, p. 88.

<sup>(&</sup>lt;sup>2</sup>) Commission Delegated Directive 2014/73/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in platinized platinum electrodes used for conductivity measurements (OJ L 148, 20.5.2014, p. 80).

<sup>(3)</sup> 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) and establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

- (9) It is, therefore, appropriate to grant the renewal of the exemption.
- (10) The exemption should be renewed for the maximum duration of 7 years until 31 December 2025, in accordance with Article 4(3) and the third subparagraph of Article 5(2) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.
- (11) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

# Article 1

Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

# Article 2

1. Member States shall adopt and publish, by 31 March 2021 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 April 2021.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 December 2019.

'37.

#### ANNEX

In Annex IV to Directive 2011/65/EU, entry 37 is replaced by the following:

- Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies:
  - (a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0,1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations;
  - (b) measurements of solutions where an accuracy of +|-1 % of the sample range and where high corrosion resistance of the electrode are required for any of the following:
    - (i) solutions with an acidity < pH 1;
    - (ii) solutions with an alkalinity > pH 13;
    - (iii) corrosive solutions containing halogen gas;
  - (c) measurements of conductivities above 100 mS/m that must be performed with portable instruments.

Expires on 31 December 2025.'

#### COMMISSION DELEGATED DIRECTIVE (EU) 2020/361

#### of 17 December 2019

amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (1), and in particular Article 5(1)(a) thereof,

- (1) Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That restriction does not apply to the exempted applications listed in Annex III to Directive 2011/65/EU.
- (2) The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive.
- (3) Hexavalent chromium is a restricted substance listed in Annex II to Directive 2011/65/EU.
- (4) An exemption from the restriction for the use of hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution ('the exemption') is included in Annex III to Directive 2011/65/EU. For categories 1 to 7 and 10, the exemption was to expire on 21 July 2016 in accordance with the second subparagraph of Article 5(2) of that Directive.
- (5) The Commission received an application for renewal of the exemption ('the renewal request') on 20 January 2015, that is within the time limit laid down in Article 5(5) of Directive 2011/65/EU. In accordance with that provision, the exemption remains valid until a decision on the renewal request has been adopted.
- (6) The evaluation of the renewal request included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU. The evaluation, taking into account the Commission Decisions on authorisations for the placing on the market for the use and/or for use of substances listed in Annex XIV to Regulation (EC) No 1907/2006 (<sup>2</sup>), led to the conclusion that the current exemption with regard to categories 1 to 7 and 10 is to be divided into two subentries with wording clearly reflecting the scientific and technical progress as regards to substitution of hexavalent chromium, which differs depending on the type of application.
- (7) Hexavalent chromium (Cr(VI)) acts as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators. It is used to create a layer on the interior surface of the steel tubes to protect them from the cooling solution that contains corrosive ammonia.

<sup>&</sup>lt;sup>(1)</sup> OJ L 174, 1.7.2011, p. 88.

<sup>(2)</sup> Summary of European Commission Decisions on authorisations for the placing on the market for the use and/or for use of substances listed in Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ C 48, 15.2.2017, p. 9).

- (8) For applications with power input ≥ 75 W and for systems fully operating with non-electrical heaters (corresponding to high boiler temperature applications) which are covered by the current exemption, a substitution or elimination of hexavalent chromium is still scientifically and technically impracticable due to the lack of reliable substitutes. An exemption for these applications is in line with Regulation (EC) No 1907/2006 of the European Parliament and of the Council (<sup>3</sup>) and thus does not weaken the environmental and health protection afforded by it.
- (9) It is, therefore, appropriate to grant the requested renewal for applications using high boiler temperatures until 21 July 2021, in accordance with Article 4(3) and the second subparagraph of Article 5(2) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.
- (10) For applications with power input < 75 W (corresponding to low boiler temperature) currently covered by the exemption, the conditions for renewal set out in Article 5(1) of Directive 2011/65/EU are no longer fulfilled and therefore, the renewal request should be rejected. In accordance with Article 5(6) of that Directive, the exemption for those applications should expire 12 months after the date of entry into force of this Directive.
- (11) For categories 8, 9 and 11, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU. For reasons of legal clarity, the dates of expiry should be specified in Annex III to that Directive.
- (12) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Annex III to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

#### Article 2

1. Member States shall adopt and publish, by 31 March 2021 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 April 2021.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 3

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

<sup>(&</sup>lt;sup>3</sup>) 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) and establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

# Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 December 2019.

# ANNEX

In Annex III to Directive 2011/65/EU, entry 9 is replaced by the following:

·9	Hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution	<ul> <li>Applies to categories 8, 9 and 11 and expires on:</li> <li>21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments,</li> <li>21 July 2023 for category 8 in vitro diagnostic medical devices,</li> <li>21 July 2024 for category 9 industrial monitoring and control instruments, and for category 11.</li> </ul>
9(a)-I	Up to 0,75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators (including minibars) designed to operate fully or partly with elec- trical heater, having an average utilised power input < 75 W at constant running conditions	Applies to categories 1-7 and 10 and expires on 5 March 2021.
9(a)-II	<ul> <li>Up to 0,75 % hexavalent chromium by weight, used as an anticorrosion agent in the cooling solution of carbon steel cooling systems of absorption refrigerators:</li> <li>designed to operate fully or partly with electrical heater, having an average utilised power input ≥ 75 W at constant running conditions,</li> <li>designed to fully operate with non-electrical heater.</li> </ul>	Applies to categories 1-7 and 10 and expires on 21 July 2021.'

#### COMMISSION DELEGATED DIRECTIVE (EU) 2020/362

#### of 17 December 2019

amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on endof-life vehicles as regards the exemption for hexavalent chromium as anti-corrosion agent of the carbon steel cooling system in absorption refrigerators in motor caravans

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-oflife vehicles (<sup>1</sup>), and in particular Article 4(2)(b) thereof,

Whereas:

- (1) Pursuant to Article 4(2)(a) of Directive 2000/53/EC, Member States are to prohibit the use of lead, mercury, cadmium and hexavalent chromium in materials and components of vehicles put on the market after 1 July 2003.
- (2) Annex II to Directive 2000/53/EC lists vehicle materials and components exempt from the prohibition pursuant to Article 4(2)(a) thereof. Exemption 14 regarding the use of hexavalent chromium needs to be amended to align for coherence the wording of that exemption with similar exemptions for the use of hexavalent chromium provided for in Directive 2011/65/EU of the European Parliament and of the Council (<sup>2</sup>) and Regulation (EC) No 1907/2006 of the European Parliament and of the Council (<sup>3</sup>).
- (3) The assessment of exemption 14 in view of technical and scientific progress led to the conclusion that although suitable alternative substances to hexavalent chromium have become available, they cannot yet be used in products. It is expected that suitable alternatives to the use of hexavalent chromium may become available in the future. It is hence appropriate to split the current exemption in three sub-entries and set an expiry date for two of the subentries to the exemption.
- (4) Directive 2000/53/EC should therefore be amended accordingly.

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Annex II to Directive 2000/53/EC is amended as set out in the Annex to this Directive.

# Article 2

1. Member States shall adopt and publish by 5 April 2020 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

<sup>&</sup>lt;sup>(1)</sup> OJ L 269, 21.10.2000, p. 34.

<sup>&</sup>lt;sup>(2)</sup> Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

<sup>(3)</sup> 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).

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law, which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 December 2019.

# ANNEX

In Annex II to Directive 2000/53/EC, entry 14 is replaced by the following:

<ul> <li>14. Hexavalent chromium as an anti-corrosion agent of the carbon steel cooling system in absorption refrigerators up to 0,75 % by weight in the cooling solution:</li> <li>(i) designed to operate fully or partly with electrical heater, having an average utilised electrical power input &lt; 75W at constant running conditions;</li> <li>(ii) designed to operate fully or partly with electrical heater, having an average utilised electrical power input &lt; 75W at constant running conditions;</li> <li>(iii) designed to operate fully or partly with electrical heater, having an average utilised electrical power input ≥ 75W at constant running conditions;</li> <li>(iii) designed to fully operate with non-electrical heater.</li> </ul>	Vehicles type approved before X' 1 January 2020 and spare parts for these vehicles Vehicles type approved before 1 January 2026 and spare parts for these vehicles
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#### COMMISSION DELEGATED DIRECTIVE (EU) 2020/363

#### of 17 December 2019

amending Annex II to Directive 2000/53/EC of the European Parliament and of the Council on endof-life vehicles as regards certain exemptions for lead and lead compounds in components

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

EN

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

Having regard to Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles (1), and in particular Article 4(2)(b) thereof,

- (1) Pursuant to Article 4(2)(a) of Directive 2000/53/EC, Member States are to prohibit the use of lead, mercury, cadmium and hexavalent chromium in materials and components of vehicles put on the market after 1 July 2003.
- (2) Annex II to Directive 2000/53/EC lists vehicle materials and components exempt from the prohibition pursuant to Article 4(2)(a) thereof. Pursuant to Annex II, exemptions 8(e), 8(f)(b) and 8(g) are to be reviewed in 2019. Exemption 8(j) also needs to be re-assessed in view of the latest information on technical and scientific progress.
- (3) An assessment of exemptions 8(e) and 8(g) in view of that information led to the conclusion that there are currently no suitable alternatives to the use of lead for the materials and components covered by those exemptions. A date for a new review of those exemptions should therefore be set. Exemption 8(g), however, should be further specified with a more narrow scope. In order to allow the automotive industry to adapt to those changes, the current scope of exemption 8(g) should be maintained for vehicles of a type approved before 1 October 2022, while the narrower scope of that exemption should apply for vehicles of a type approved from that date.
- (4) The assessment of exemption 8(f)(b) leads to the conclusion that the use of lead in the applications covered by that exemption should not be prolonged because there are alternatives to the use of lead in those applications.
- (5) The assessment of exemption 8(j) which gives an exemption to the use of lead in solders for soldering of laminated glazing led to the conclusion that, for some applications, there are alternatives to the use of lead in solders for soldering of laminated glazing. However, there are some glass panes and applications for which there is no certainty that suitable alternatives to the use of lead exist at this time. It is therefore appropriate to lay down a new, more limited, exemption 8(k) for those glass panes and applications.
- (6) Exemption 8(j) applies only with respect to vehicles of a type approved before 1 January 2020. In order to ensure that the use of lead continues to be exempted for those glass panes and applications for which there is no certainty that suitable alternatives to the use of lead exist at this time, it is necessary for the new exemption 8(k) to apply as soon as possible. Therefore, this Directive should enter into force as a matter of urgency.
- (7) Directive 2000/53/EC should therefore be amended accordingly,

<sup>(1)</sup> OJ L 269, 21.10.2000, p. 34.

HAS ADOPTED THIS DIRECTIVE:

# Article 1

Annex II to Directive 2000/53/EC is amended as set out in the Annex to this Directive.

# Article 2

1. Member States shall adopt and publish by 5 April 2020 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law, which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 December 2019.

# ANNEX

Annex II to Directive 2000/53/EC is amended as follows:

(1) entry 8(e) is replaced by the following:

'8(e). Lead in high melting temperature type solders (i.e. lead-	(2)	X'
based alloys containing 85 % by weight or more lead)		

(2) entry 8(f)(b) is replaced by the following:

<sup>(8</sup> (f)(b). Lead in compliant pin connector systems other than the mating area of vehicle harness connectors	Vehicles type-approved before 1 Janu ary 2024 and spare parts for these ve- hicles	X'
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# (3) entry 8(g) is replaced by the following:

<sup>6</sup> 8(g)(i). Lead in solders to complete a viable electrical con- nection between semiconductor die and carrier within in- tegrated circuit flip chip packages	Vehicles type approved before 1 Octo ber 2022 and spare parts for these ve- hicles	Х
<ul> <li>8(g)(ii). Lead in solders to complete a viable electrical connection between the semiconductor die and the carrier within integrated circuit flip chip packages where that electrical connection consists of any of the following:</li> <li>(i) a semiconductor technology node of 90 nm or larger;</li> <li>(ii) a single die of 300 mm<sup>2</sup> or larger in any semiconductor technology node;</li> <li>(iii) stacked die packages with dies of 300 mm<sup>2</sup> or larger, or silicon interposers of 300 mm<sup>2</sup> or larger.</li> </ul>	<sup>(?)</sup> Valid for vehicles type-approved from 1 October 2022 and spare parts for these vehicles	Χ'

(4) the following entry 8(k) is inserted:

<sup>'8</sup> (k). Soldering of heating applications with 0,5 A or more of heat current per related solder joint to single panes of laminated glazings not exceeding wall thickness of 2,1 mm. This exemption does not cover soldering to contacts em- bedded in the intermediate polymer	Vehicles type approved before 1 Janu ary 2024 and spare parts for these ve- hicles	X(*)'
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#### COMMISSION DELEGATED DIRECTIVE (EU) 2020/364

#### of 17 December 2019

amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of cadmium in certain radiation tolerant video camera tubes

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (1), and in particular Article 5(1)(a) thereof,

- (1) Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That restriction does not apply to certain exempted applications which are specific to medical devices and monitoring and control instruments and are listed in Annex IV to that Directive.
- (2) The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive.
- (3) Cadmium is a restricted substance listed in Annex II to Directive 2011/65/EU.
- (4) On 3 December 2015, the Commission received an application made in accordance with Article 5(3) of Directive 2011/65/EU for an exemption to be listed in Annex IV to that Directive, for the use of cadmium in certain radiation tolerant video camera tubes ('the requested exemption').
- (5) The evaluation of the request included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.
- (6) Cadmium in video camera tubes is necessary to achieve satisfactory radiation tolerance and optical performance of video cameras operating in environments with high radiation exposure, such as nuclear power plants and nuclear waste reprocessing facilities.
- (7) Currently, there are no cadmium-free alternatives available on the market which would provide the necessary combination of optical performance and sufficient radiation resistance.
- (8) Due to the lack of alternatives, a substitution or elimination of cadmium is scientifically and technically impracticable for certain video camera tubes. The exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council (<sup>2</sup>) and thus does not weaken the environmental and health protection afforded by it.
- (9) It is, therefore, appropriate to grant the requested exemption by including the applications covered by it in Annex IV to Directive 2011/65/EU with respect to electrical and electronic equipment of category 9.
- (10) The requested exemption should be granted for a duration of 7 years starting from 5 March 2020, in accordance with the first subparagraph of Article 5(2) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.
- (11) Directive 2011/65/EU should therefore be amended accordingly,

<sup>&</sup>lt;sup>(1)</sup> OJ L 174, 1.7.2011, p. 88.

<sup>(2)</sup> 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) and establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

HAS ADOPTED THIS DIRECTIVE:

# Article 1

Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

#### Article 2

1. Member States shall adopt and publish, by 31 August 2020 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 September 2020.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 December 2019.

# ANNEX

In Annex IV to Directive 2011/65/EU, the following entry 44 is added:

'44. Cadmium in radiation tolerant video camera tubes designed for cameras with a centre resolution greater than 450 TV lines which are used in environments with ionising radiation exposure exceeding 100 Gy/hour and a total dose in excess of 100kGy.

Applies to category 9. Expires on 31 March 2027.'

# COMMISSION DELEGATED DIRECTIVE (EU) 2020/365

#### of 17 December 2019

amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders and termination finishes used in certain hand-held combustion engines

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (<sup>1</sup>), and in particular Article 5(1)(a) thereof,

- (1) Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That restriction does not apply to the exempted applications listed in Annex III to Directive 2011/65/EU.
- (2) The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive.
- (3) Lead is a restricted substance listed in Annex II to Directive 2011/65/EU.
- (4) By Delegated Directive (EU) 2014/72/EU (<sup>2</sup>), the Commission granted an exemption for the use of lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council (<sup>3</sup>)) ("the exemption") by including those applications in Annex III to Directive 2011/65/EU. The exemption was to expire for categories 1 to 7 and 10 on 31 December 2018, in accordance with the second subparagraph of Article 5(2) of that Directive.
- (5) The Commission received an application for renewal of the exemption for categories 6 and 11 ("the renewal request") on 30 June 2017, that is within the time limit laid down in Article 5(5) of Directive 2011/65/EU. In accordance with that provision, the exemption remains valid until a decision on the renewal request has been adopted.
- (6) The evaluation of the renewal request included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.

<sup>&</sup>lt;sup>(1)</sup> OJ L 174, 1.7.2011, p. 88.

<sup>(&</sup>lt;sup>2</sup>) Commission Delegated Directive 2014/72/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems (OJ L 148, 20.5.2014, p. 78).

<sup>(&</sup>lt;sup>3</sup>) Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1). Directive 97/68/EC has been repealed by Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).

- (7) Lead is a common alloying element in solder material to control the melting point. Alternative materials to replace the restricted substance have been successfully tested. However, additional time is needed to confirm the reliability of the lead-free products.
- (8) Currently, there are no lead-free alternatives available on the market which would provide sufficient level of reliability for the applications covered by the exemption.
- (9) Due to the lack of reliable alternatives, a substitution or elimination of lead is currently scientifically and technically impracticable for certain hand-held combustion engines. It is, therefore, appropriate, to renew the exemption. The renewal of the exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council (\*) and thus does not weaken the environmental and health protection afforded by it.
- (10) The exemption for categories 1 to 7, 10 and 11 should be renewed until 31 March 2022, in accordance with Article 4(3) and the first subparagraph of Article 5(2) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.
- (11) For categories 8 and 9, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU. For reasons of legal clarity, the dates of expiry should be specified in Annex III to that Directive.
- (12) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Annex III to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

# Article 2

1. Member States shall adopt and publish, by 31 March 2021 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 April 2021.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 3

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

<sup>(4)</sup> 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) and establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

# Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 December 2019.

# ANNEX

In Annex III to Directive 2011/65/EU, entry 41 is replaced by the following:

'41	Lead in solders and termination finishes of electri- cal and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control sys- tems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand- held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council (*))	<ul> <li>Applies to all categories and expires on:</li> <li>31 March 2022 for categories 1 to 7, 10 and 11;</li> <li>21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;</li> <li>21 July 2023 for category 8 in vitro diagnostic medical devices;</li> <li>21 July 2024 for category 9 industrial monitoring and control instruments.</li> </ul>
Membe	re 97/68/EC of the European Parliament and of the Counci r States relating to measures against the emission of gaseous l in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).'	l of 16 December 1997 on the approximation of the laws of the and particulate pollutants from internal combustion engines to be

#### COMMISSION DELEGATED DIRECTIVE (EU) 2020/366

#### of 17 December 2019

amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (<sup>1</sup>), and in particular Article 5(1)(a) thereof,

- (1) Article 4(1) of Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That restriction does not apply to certain exempted applications which are specific to medical devices and monitoring and control instruments and are listed in Annex IV to that Directive.
- (2) The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive.
- (3) Lead is a restricted substance listed in Annex II to Directive 2011/65/EU.
- (4) By Delegated Directive (EU) 2015/573 (<sup>2</sup>), the Commission granted an exemption for the use of lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases ('the exemption'), by including that application in Annex IV to Directive 2011/65/EU. The exemption was to expire on 31 December 2018, in accordance with the third subparagraph of Article 5(2) of that Directive.
- (5) The Commission received an application for renewal of the exemption ('the renewal request') on 25 May 2017, that is within the time limit laid down in Article 5(5) of Directive 2011/65/EU. In accordance with that provision, the exemption remains valid until a decision on the renewal request has been adopted.
- (6) The evaluation of the renewal request included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.
- (7) Lead in the PVC sensor card of concerned in vitro medical devices (blood analysers) enhances sensor performance which is necessary for the optimum performance of the device in terms of analytical reliability claimed in product publications and thus for fulfilment of requirements laid down in Directive 98/79/EC of the European Parliament and of the Council (<sup>3</sup>).
- (8) While lead-free technologies are available on the market for certain analysers of other manufacturers, reliability testing of substitutes for the specific application subject to the current renewal request requires additional time.

<sup>(&</sup>lt;sup>1</sup>) OJ L 174, 1.7.2011, p. 88.

<sup>(&</sup>lt;sup>2</sup>) Commission Delegated Directive (EU) 2015/573 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices (OJ L 94, 10.4.2015, p. 4).

<sup>&</sup>lt;sup>(3)</sup> Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

- (9) Discontinuation of the exemption is expected to avoid a total of 157 kg of lead being placed on the Union market. At the same time, however, it will result in the need to replace the entire diagnostic device, and consequently, is expected to lead to a premature generation of 112 000 kg of waste electrical and electronic equipment. Furthermore, significant socioeconomic impacts on health providers using the devices concerned would be incurred.
- (10) The exemption does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 of the European Parliament and of the Council. (4) In light of the restriction process on lead in PVC provided for in Regulation (EC) No 1907/2006, the exemption should be granted for a short validity period of 2 years to ensure full alignment with that Regulation once the relevant restriction process is concluded.
- (11) It is, therefore, appropriate to grant the renewal of the exemption.
- (12) The exemption concerns category 8 of electrical and electronic equipment to which Directive 2011/65/EU applies and it should be renewed for the duration of 2 years starting from 5 March 2020, in accordance with the third subparagraph of Article 5(2) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.
- (13) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

#### Article 2

1. Member States shall adopt and publish, by 31 March 2021 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 April 2021.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 December 2019.

<sup>(4)</sup> 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) and establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

# ANNEX

In Annex IV to Directive 2011/65/EU, entry 41 is replaced by the following:

'41. Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.

Expires on 31 March 2022.'

# COMMISSION DIRECTIVE (EU) 2020/367

#### of 4 March 2020

amending Annex III to Directive 2002/49/EC of the European Parliament and of the Council as regards the establishment of assessment methods for harmful effects of environmental noise

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise (1), and in particular Article 12 thereof,

- (1) Annex III to Directive 2002/49/EC refers to dose-effect relations to be introduced by way of adaptations of that Annex to technical and scientific progress.
- (2) At the time of adoption of this Directive, the high quality and statistically significant information that could be used was that of the World Health Organisation (WHO) Environmental Noise Guidelines for the European Region (<sup>2</sup>), presenting dose-effect relations for harmful effects induced by the exposure to environmental noise. Consequently, the dose-effect relations introduced in Annex III to Directive 2002/49/EC should be based on those guidelines. In particular concerning the statistical significance, the WHO studies were based on representative populations, and the results of these assessment methods are consequently considered relevant when applied to representative populations.
- (3) Beyond the dose-effect relations developed in the context of the WHO, other studies might show different health effect sizes and other health effects, in particular concerning effects of road, railway and aircraft noise in local situations in specific countries. The alternative dose-effect relations established therein could be used provided that they are based on high quality and statistically significant studies.
- (4) Currently, limited knowledge is available on the harmful effects of industrial noise so that it is not possible to propose a common method for their assessment. Also, country specificities were not assessed in studies and therefore could not be included in this Annex. Likewise, while links between environmental noise and the following harmful effects were found, there is currently no sufficient evidence for determining a common method for the assessment of those harmful effects: stroke, hypertension, diabetes and other metabolic health outcomes, cognitive impairment in children, mental health and wellbeing, hearing impairment, tinnitus, adverse birth outcomes. Finally, while the link between railway noise and aircraft noise to the ischaemic heart disease (IHD) is established, for these two sources the quantification of the increased risk of IHD is premature.

<sup>(&</sup>lt;sup>1</sup>) OJ L 189, 18.7.2002, p. 12.

<sup>(2)</sup> Environmental Noise Guidelines for the European Region, World Health Organisation 2018, ISBN 978 92 890 5356 3.

- (5) Directive 2002/49/EC should therefore be amended accordingly.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Committee established under Article 13 of Directive 2002/49/EC,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Annex III to Directive 2002/49/EC is replaced by the text in the Annex to this Directive.

#### Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2021 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 4 March 2020.

For the Commission Virginijus SINKEVIČIUS Member of the Commission

#### ANNEX

## 'ANNEX III

# ASSESSMENT METHODS FOR HARMFUL EFFECTS

# (Referred to in Article 6(3))

# 1. Set of harmful effects

For the purposes of the assessment of harmful effects the following shall be considered:

- ischaemic heart disease (IHD) corresponding to codes BA40 to BA6Z of the international classification ICD-11 established by the World Health Organisation;
- high annoyance (HA);
- high sleep disturbance (HSD).

#### 2. Calculation of harmful effects

The harmful effects shall be calculated by either of the following:

- the relative risk (RR) of a harmful effect defined as

$$RR = \begin{pmatrix} Probability of occurrence of the harmful effect \\ in a population exposed \\ to a specific level of environmental noise \\ \hline Probability of occurrence of the harmful effect \\ in a population non exposed \\ to environmental noise \\ \hline \end{pmatrix}$$
(Formula 1)

— the absolute risk (AR) of a harmful effect defined as

$$AR = \begin{pmatrix} Occurrence of the harmful effect \\ in a population exposed \\ to a specific level of environmental noise \end{pmatrix}$$
(Formula 2)

#### 2.1. IHD

For the calculation of the RR, with respect to the harmful effect of IHD and concerning the incidence rate (i), the following dose-effect relations shall be used:

$$RR_{IHD,i,road} = \begin{cases} e^{\left[\binom{ln(1.08)}{10}*(L_{den}-53)\right]} & \text{for } L_{den} \text{ greater than 53 } dB\\ 1 & \text{for } L_{den} \text{ equal or smaller than 53 } dB \end{cases}$$

(Formula 3)

for road noise.

#### 2.2. HA

For the calculation of the AR, with respect to the harmful effect of HA the following dose-effect relations shall be used:

$$AR_{HA,road} = \frac{\left(78.9270 - 3.1162 * L_{den} + 0.0342 * L_{den}^{2}\right)}{100}$$
(Formula 4)

for road noise;

$$AR_{HA,rail} = \frac{\left(38.1596 - 2.05538 * L_{den} + 0.0285 * L_{den}^{2}\right)}{100}$$
(Formula 5)

for railway noise;

$$AR_{HA,air} = \frac{\left(-50.9693 + 1.0168 * L_{den} + 0.0072 * L_{den}^{2}\right)}{100}$$
(Formula 6)

for aircraft noise.

#### 2.3. HSD

For the calculation of the AR, with respect to the harmful effect of HSD the following dose-effect relations shall be used:

$$AR_{HSD,road} = \frac{\left(19.4312 - 0.9336 * L_{night} + 0.0126 * L_{night}^{2}\right)}{100} (\text{Formula 7})$$

for road noise;

$$AR_{HSD,rail} = \frac{\left(67.5406 - 3.1852 * L_{night} + 0.0391 * L_{night}^{2}\right)}{100} (\text{Formula 8})$$

for railway noise;

$$AR_{HSD,air} = \frac{\left(16.7885 - 0.9293 * L_{night} + 0.0198 * L_{night}^{2}\right)}{100} (\text{Formula 9})$$

for aircraft noise.

#### 3. Assessment of harmful effects

3.1. The exposure of the population shall be assessed independently for each noise source and harmful effect. Where the same people are simultaneously exposed to different noise sources, the harmful effects may -in general- not be cumulated. However, those effects may be compared to assess the relative importance of each noise.

# 3.2. Assessment for IHD

- 3.2.1. For IHD in the case of railway and aircraft noise, the population exposed above adequate L<sub>den</sub> levels is estimated as subject to an increased risk of IHD, while the exact number N of cases of IHD cannot be calculated.
- 3.2.2. **For IHD in the case of road noise,** the proportion of cases of the specific harmful effect in the population exposed to a RR that is calculated to be caused by environmental noise is derived, for the noise source *x* (road), harmful effect *y* (IHD) and for the incidence *i* by:

$$PAF_{x,y} = \left(\frac{\sum_{j} [p_{j} \cdot (RR_{j,x,y}-1)]}{\sum_{j} [p_{j} \cdot (RR_{j,x,y}-1)]+1}\right) (\text{Formula 10})$$

# Where:

- $PAF_{x,y}$  is the population attributable fraction,
- the set of *j* noise bands is made up of single bands spanning over a maximum of 5 dB (e.g.: 50-51 dB, 51-52 dB, 52-53 dB, etc. or 50-54 dB, 55-59 dB, 60-64 dB, etc.),
- $p_j$  is the proportion of the overall population *P* in the area assessed that is exposed to the *j*-th exposure band, which is associated with a given RR of a specific harmful effect  $RR_{j,x,y}$ . The  $RR_{j,x,y}$  is calculated using the formulas described in point 2 of this Annex, calculated at the central value of each noise band (e.g.: depending on availability of data, at 50,5 dB for the noise band defined between 50-51 dB, or 52 dB for the noise band 50-54 dB).
- 3.2.3. **For IHD in the case of road noise, the total number N of cases of IHD** (people affected by the harmful effect *y*; number of attributable cases) due to the source *x* is then:

 $N_{x,y} = PAF_{x,y,i} * I_y * P$  (Formula 11)

for road.

Where:

- $PAF_{x,y,i}$  is calculated for the incidence *i*,
- Iv is the incidence rate of IHD in the area under assessment, that can be obtained from statistics on health for the region or country where the area is,
- P is the total population of the area under assessment (the sum of the population in the different noise bands).
- 3.3. For HA and HSD in the case of road, railway and aircraft noise, the total number N of people affected by the harmful effect *y* (number of attributable cases) due to the source *x*, for each combination of noise source *x* (road, railway or aircraft source) and harmful effect *y* (HA, HSD), is then:

 $N_{x,y} = \sum_{j} [n_j * AR_{j,x,y}]$  (Formula 12)

Where:

- AR<sub>xy</sub> is the AR of the relevant harmful effect (HA, HSD), and is calculated using the formulas set out in point 2 of this Annex, calculated at the central value of each noise band (e.g.: depending on availability of data, at 50,5 dB for the noise band defined between 50-51 dB, or 52 dB for the noise band 50-54 dB),
- $n_j$  is the number of people that is exposed to the *j*-th exposure band.

# 4. Future revisions

The dose-effect relations introduced by future revisions of this Annex will concern in particular:

- the relation between annoyance and L<sub>den</sub> for industrial noise,
- the relation between sleep disturbance and  $L_{\mbox{\scriptsize night}}$  for industrial noise.

If necessary, specific dose-effect relations could be presented for:

- dwellings with special insulation against noise as defined in Annex VI,
- dwellings with a quiet façade as defined in Annex VI,
- different climates/different cultures,
- vulnerable groups of the population,
- tonal industrial noise,
- impulsive industrial noise and other special cases.'

# DECISIONS

# **COMMISSION IMPLEMENTING DECISION (EU) 2020/368**

# of 3 March 2020

approving the plan for the eradication of African swine fever in feral pigs in certain areas of Slovakia

(notified under document C(2020) 1157)

(Only the Slovak text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever (<sup>1</sup>), and in particular the second subparagraph of Article 16(1) thereof,

- (1) Directive 2002/60/EC lays down the minimum Union measures to be taken for the control of African swine fever, including those to be applied in the event of confirmation of a case of African swine fever in feral pigs.
- (2) In addition, Commission Implementing Decision 2014/709/EU (<sup>2</sup>) lays down animal health control measures in relation to African swine fever in the Member States or areas thereof as listed in the Annex thereto (the Member States concerned), and in all Member States as regards movements of feral pigs and information obligations. The Annex to Implementing Decision 2014/709/EU demarcates and lists certain areas of the Member States concerned, differentiated by the level of risk based on the epidemiological situation as regards that disease, including a list of high risk areas. That Annex has been amended several times to take account of changes in the epidemiological situation in the Union as regards African swine fever that needed to be reflected in that Annex.
- (3) In 2019, Slovakia notified the Commission of cases of African swine fever in feral pigs and has duly taken the disease control measures required by Directive 2002/60/EC.
- (4) In light of the current epidemiological situation and in accordance with Article 16 of Directive 2002/60/EC, Slovakia submitted to the Commission a plan for the eradication of African swine fever on 27 November 2019 (the eradication plan).

<sup>&</sup>lt;sup>(1)</sup> OJ L 192, 20.7.2002, p. 27.

<sup>(&</sup>lt;sup>2</sup>) Commission Implementing Decision 2014/709/EU of 9 October 2014 concerning animal health control measures relating to African swine fever in certain Member States and repealing Implementing Decision 2014/178/EU (OJ L 295, 11.10.2014, p. 63).

- (5) The Annex to Implementing Decision 2014/709/EU was latest amended by Commission Implementing Decision (EU) 2020/46 (<sup>3</sup>) to take account, inter alia, of the cases of African swine fever in feral pigs in Slovakia and Parts I and II of that Annex now include the infected areas in Slovakia.
- (6) The eradication plan submitted by Slovakia has been examined by the Commission and found to comply with the requirements set out in Article 16 of Directive 2002/60/EC. The eradication plan should therefore be approved accordingly.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

The plan submitted by Slovakia on 27 November 2019, in accordance with Article 16(1) of Directive 2002/60/EC, concerning the eradication of African swine fever from the feral pig population in the areas referred to in the Annex to Implementing Decision 2014/709/EU is hereby approved.

Article 2

Slovakia shall bring into force the laws, regulations and administrative provisions required for the implementation of the eradication plan within a period of 30 days from the date of adoption of this Decision.

Article 3

This Decision is addressed to Slovak Republic.

Done at Brussels, 3 March 2020.

For the Commission Stella KYRIAKIDES Member of the Commission

<sup>(&</sup>lt;sup>3</sup>) Commission Implementing Decision (EU) 2020/46 of 20 January 2020 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States (OJ L 16, 21.1.2020, p. 9).

# COMMISSION DECISION (EU) 2020/369

#### of 4 March 2020

conferring the power to issue an external alert on entities representing consumer and trader interests at a Union level pursuant to Regulation (EU) 2017/2394 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/2394 of the European Parliament and of the Council of 12 December 2017 on cooperation between national authorities responsible for the enforcement of consumer protection laws and repealing Regulation (EC) No 2006/2004 (<sup>1</sup>), and in particular Article 27(2) thereof,

Whereas:

- (1) Regulation (EU) 2017/2394 lays down provisions for cooperation between competent authorities designated by Member States as responsible for the enforcement of Union laws that protect consumers' interests.
- (2) Article 27(2) of Regulation (EU) 2017/2394 requires the Commission, to confer the power to issue 'external alerts' concerning suspected infringements covered by that Regulation on entities representing consumer, and, where appropriate, trader, interests at a Union level.
- (3) The entities covered by this Decision operate on a Union level and expressed interest in participating in the external alert mechanism. Those entities have signed up to the Transparency Register and thereby to the Code of Conduct contained in Annex III of the Agreement between the European Parliament and the European Commission on the transparency register for organisations and self-employed individuals engaged in EU policy-making and policy implementation (<sup>2</sup>).
- (4) Regulation (EU) 2017/2394 applies from 17 January 2020. This Decision should therefore apply from the day following that of its publication in the *Official Journal of the European Union* in order to enable the organisations concerned to participate in the external alert mechanism as soon as possible.
- (5) In line with Article 27(2) of Regulation (EU) 2017/2394 Member States were consulted on the entities covered by this Decision,

HAS ADOPTED THIS DECISION:

Article 1

The power to issue an external alert pursuant to Article 27(2) of Regulation (EU) 2017/2394 shall be conferred on the following entities:

<sup>(&</sup>lt;sup>1</sup>) OJ L 345, 27.12.2017, p. 1

<sup>&</sup>lt;sup>(2)</sup> OJ L 277, 19.9.2014, p. 11.

- (a) the European Consumer Organisation (BEUC), Identification number in the Transparency Register: 9505781573-45;
- (b) the Confederation of Family Organisations in the European Union (COFACE), Identification number in the Transparency Register: 93283396780-85;
- (c) the European Community of Consumer Co-operatives (EURO COOP), Identification number in the Transparency Register: 3819438251-87.

Article 2

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

Done at Brussels, 4 March 2020.

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