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⁽¹⁾ Text with EEA relevance.

EN

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II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2021/667**of 23 April 2021****implementing Article 21(2) of Regulation (EU) 2016/44 concerning restrictive measures in view of the situation in Libya**

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) 2016/44 of 18 January 2016 concerning restrictive measures in view of the situation in Libya and repealing Regulation (EU) No 204/2011 ⁽¹⁾, and in particular Article 21(2) thereof,

Having regard to the proposal of the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 18 January 2016, the Council adopted Regulation (EU) 2016/44.
- (2) The entry for one person should be deleted as he is deceased.
- (3) Annex III to Regulation (EU) 2016/44 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EU) 2016/44 is amended in accordance with the Annex to this Regulation.

*Article 2*This Regulation shall enter into force on the 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, 23 April 2021.

For the Council
The President
A. P. ZACARIAS

⁽¹⁾ OJ L 12, 19.1.2016, p. 1.

ANNEX

In Regulation (EU) 2016/44, Annex III (List of natural and legal persons, entities or bodies referred to in Article 6(2)), Part A (Persons), entry 9 (concerning AL-GAOUD, Abdelmajid) is deleted.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/668**of 23 April 2021****authorising a change of the conditions of use of chia seeds (*Salvia hispanica*) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) Commission Decision 2009/827/EC ⁽³⁾ authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽⁴⁾, the placing on the market in the Union of chia seeds (*Salvia hispanica*) as a novel food to be used in bread products.
- (4) Commission Implementing Decision 2013/50/EU ⁽⁵⁾ authorised, in accordance with Regulation (EC) No 258/97, an extension of use of chia seeds as a novel food to be used in additional food categories as follows: baked products; breakfast cereals; fruit, nut and seed mixes and pre-packaged chia seeds as such.
- (5) On 18 September 2015, the competent authority of Ireland issued an official letter ⁽⁶⁾ in accordance with Regulation (EC) No 258/97, authorising an extension of use of the novel food chia seeds in additional food categories, namely fruit juice and fruit/vegetable blend beverages.
- (6) On 17 October 2017, the competent authority of Austria issued an official letter ⁽⁷⁾ in accordance with Regulation (EC) No 258/97, authorising an extension of use of the novel food chia seeds in an additional food category, namely fruit spreads.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Commission Decision 2009/827/EC of 13 October 2009 authorising the placing on the market of Chia seed (*Salvia hispanica*) as novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 294, 11.11.2009, p. 14).

⁽⁴⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

⁽⁵⁾ Commission Implementing Decision 2013/50/EU of 22 January 2013 authorising an extension of use of Chia (*Salvia hispanica*) seed as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 21, 24.1.2013, p. 34).

⁽⁶⁾ Letter of 18 September 2015 (https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2015_auth-letter_chia-seeds-2_en.pdf).

⁽⁷⁾ Letter of 17 October 2017 (https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2017_auth-letter_chia-seeds_en.pdf).

- (7) On 2 November 2017, the competent authority of Spain issued an official letter ⁽⁸⁾ in accordance with Regulation (EC) No 258/97, authorising an extension of use of the novel food chia seeds in additional food categories, namely sterilised ready meals based on cereal grains, pseudocereal grains and/or pulses.
- (8) Commission Implementing Decision (EU) 2017/2354 ⁽⁹⁾ authorised, in accordance with Regulation (EC) No 258/97, an extension of use of chia seeds as a novel food to be used in an additional food category, namely yoghurt.
- (9) Commission Implementing Regulation (EU) 2020/24 ⁽¹⁰⁾ authorised an extension of use of the novel food chia seeds to be used in a number of additional food categories, certain changes of the conditions of use and the specific labelling requirements of chia seeds in accordance with Regulation (EU) 2015/2283.
- (10) In line with previous authorisations, chia seeds are authorised for placing on the market within the Union under the specified conditions of use, including 'pre-packaged chia seed as such'. In January 2020, the Commission received a query from the association 'Réseau Vrac' on whether non pre-packaged (loose, bulk) chia seeds as such may also be placed on the Union market.
- (11) Following this query, the Commission has further evaluated whether the removal of the term 'pre-packaged' from the category 'pre-packaged chia seed as such' is also safe. That amendment would allow food business operators to place chia seeds as such on the Union market in both pre-packaged and non-pre-packaged (loose, bulk) forms. Therefore, the Commission is of the view that the Union list should be amended accordingly.
- (12) In accordance with Article 10(1) of Regulation (EU) 2015/2283, the Commission started the procedure for updating the Union list of novel foods on its own initiative.
- (13) In its opinion of 14 March 2019 concerning the 'Safety of chia seeds (*Salvia hispanica* L.) as a novel food for extended uses pursuant to Regulation (EU) 2015/2283' ⁽¹¹⁾, the European Food Safety Authority ('the Authority') concluded that the use of chia seeds in foods which do not require heat treatment at or above 120 °C in their manufacture, processing or preparation is safe without any specific restrictions and precautions regarding their use levels.
- (14) The Commission considers that a safety evaluation by the Authority of the proposed change to the conditions of use in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary, as the change of the conditions of use of the novel food chia seeds (*Salvia hispanica*), by removing forms in which chia seeds as such may be placed on the market is not liable to have an effect on human health.
- (15) It is therefore appropriate to authorise the placing on the market of chia seeds also without pre-packaging.
- (16) Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁸⁾ Letter of 2 November 2017 (https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2017_auth-letter_chia-seeds-ext-steri_en.pdf).

⁽⁹⁾ Commission Implementing Decision (EU) 2017/2354 of 14 December 2017 authorising an extension of use of Chia seeds (*Salvia hispanica*) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 336, 16.12.2017, p. 49).

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2020/24 of 13 January 2020 authorising an extension of use of chia seeds (*Salvia hispanica*) as a novel food and the change of the conditions of use and the specific labelling requirements of chia seeds (*Salvia hispanica*) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 8, 14.1.2020, p. 12).

⁽¹¹⁾ EFSA Journal 2019;17(4):5657.

HAS ADOPTED THIS REGULATION:

Article 1

1. The entry in the Union list of authorised novel foods as provided for in Article 6 of Regulation (EU) 2015/2283 and included in the Annex to Implementing Regulation (EU) 2017/2470, referring to the novel food chia seeds (*Salvia hispanica*), shall be amended as specified in the Annex to this Regulation.
2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in 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, 23 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The entry for 'Chia seeds (*Salvia hispanica*)' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Chia seeds (<i>Salvia hispanica</i>)'	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Chia seeds (<i>Salvia hispanica</i>)"	
	Bread products	5 % (whole or ground chia seeds)		
	Baked products	10 % whole chia seeds		
	Breakfast cereals	10 % whole chia seeds		
	Sterilised ready to eat meals based on cereal grains, pseudocereal grains and/or pulses	5 % whole chia seeds		
	Fruit, nut and seed mixes			
	Chia seeds as such			
	Confectionery (including chocolate and chocolate products), excluding chewing gums			
	Dairy products (including yoghurt) and analogues			
	Edible ices			
	Fruit and vegetables products (including fruit spreads, compotes with/without cereals, fruit-preparations to underlay or to be mixed with dairy products, fruit desserts, mixed fruits with coconut milk for a twin pot)			
	Non-alcoholic beverages (including fruit juice and fruit/vegetable blend beverages)			
	Puddings that do not require heat treatment at or above 120 °C in their manufacture, processing or preparation			

COMMISSION IMPLEMENTING REGULATION (EU) 2021/669**of 23 April 2021****concerning the authorisation of technically pure L-lysine monohydrochloride and liquid L-lysine base produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7(1) of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of liquid L-lysine base and technically pure L-lysine monohydrochloride as nutritional feed additives for use in feed and in water for drinking for all animal species. These applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The applications concern the authorisation of L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP as feed additives for all animal species to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 30 September 2020 ⁽²⁾ and 18 November 2020 ⁽³⁾ ⁽⁴⁾ that, under the proposed conditions of use, L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP do not have an adverse effect on animal health, consumer health or the environment. The Authority could conclude on the safety for the user of the L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium glutamicum* KCCM 80216 and *Corynebacterium glutamicum* KCTC 12307BP. It stated that of L-lysine monohydrochloride, technically pure, and L-lysine base, liquid, produced by *Corynebacterium casei* KCCM 80190 are considered hazardous by inhalation and that L-lysine monohydrochloride, technically pure, produced by *Corynebacterium casei* KCCM 80190 is a mild eye irritant. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP, are effective sources of the essential amino acid L-lysine for all animal species. For the supplemental L-lysine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. In its opinions, the Authority referred to a previous statement concerning potential nutritional imbalances for amino acids and hygienic concerns, when they are administered via water for drinking. However, the Authority did not propose a maximum content for the supplementation with L-lysine. Thus, it is appropriate to indicate on the label of the additive, and premixtures containing it, an alert to take into account the dietary supply with all the essential and conditionally essential amino acids, particularly in the case of supplementation with L-lysine as amino acid via water for drinking.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2020;18(11):6285.

⁽³⁾ EFSA Journal 2020;18(12): 6333.

⁽⁴⁾ EFSA Journal 2020;18(12): 6334.

- (5) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of L-lysine base, liquid, and L-lysine monohydrochloride, technically pure, produced by *Corynebacterium casei* KCCM 80190 or *Corynebacterium glutamicum* KCCM 80216 or *Corynebacterium glutamicum* KCTC 12307BP shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The substances specified in the Annex, belonging to the category 'nutritional additives' and the functional group 'amino acids, their salts and analogues', are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 23 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

Category of nutritional additives.**Functional group: amino acids, their salts and analogues.**

3c320	-	L-lysine base, liquid	<i>Additive composition:</i> Aqueous solution of L-lysine with a minimum of 50 % L-lysine.	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine base, liquid, may be placed on the market and used as an additive consisting of a preparation. 3. The additive can be also used via water for drinking. 4. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.' 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by	16 May 2031
			<i>Characterisation of the active substance:</i> L-lysine produced by fermentation with <i>Corynebacterium casei</i> KCCM 80190 Chemical formula: $\text{NH}_2\text{-(CH}_2\text{)}_4\text{-CH(NH}_2\text{)-COOH}$ CAS Number: 56-87-1						
			<i>Analytical methods ⁽¹⁾:</i> For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F).						

			For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS).					such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection, safety glasses and gloves.	
3c326	-	L-lysine base, liquid	<i>Additive composition:</i> Aqueous solution of L-lysine with a minimum of 50 % L-lysine. <i>Characterisation of the active substance:</i> L-lysine produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80216 or <i>Corynebacterium glutamicum</i> KCTC 12307BP Chemical formula: $\text{NH}_2\text{-(CH}_2\text{)}_4\text{-CH(NH}_2\text{)-COOH}$ CAS Number: 56-87-1 <i>Analytical methods ⁽¹⁾:</i> For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180.	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine base, liquid, may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with	16 May 2031

			For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS).					appropriate personal protective equipment, including breathing protection.	
3c322		L-lysine monohydrochloride, technically pure	<i>Additive composition:</i> Powder of L-lysine monohydrochloride with a minimum of 78 % L-lysine and a maximum moisture content of 1,5 %. <i>Characterisation of the active substance:</i> L-lysine monohydrochloride produced by fermentation with <i>Corynebacterium casei</i> KCCM 80190 Chemical formula: $\text{NH}_2\text{-(CH}_2\text{)}_4\text{-CH(NH}_2\text{)-COOH}$ CAS Number: 657-27-2 <i>Analytical methods</i> ⁽¹⁾:	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine monohydrochloride, technically pure, may be placed on the market and used as an additive consisting of a preparation. 3. The additive can be also used via water for drinking. 4. Declarations to be made on the labelling of the additive and premixtures: "The supplementation with L-lysine, in particular via water for drinking, should take into account	16 May 2031

			For the identification of L-lysine monohydrochloride in the feed additive: — Food Chemical Codex 'L-lysine monohydrochloride monograph' For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS).					all essential and conditionally essential amino acids in order to avoid imbalances.' 5. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m³ air ⁽²⁾. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection, safety glasses and gloves.	
3c327		L-lysine monohydrochloride, technically pure	<i>Additive composition:</i> Powder of L-lysine monohydrochloride with a minimum of 78 % L-lysine and a maximum moisture content of 1,5 %. <i>Characterisation of the active substance:</i> L-lysine monohydrochloride produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80216 or <i>Corynebacterium glutamicum</i> KCTC 12307BP Chemical formula: NH₂-(CH₂)₄-CH(NH₂)-COOH CAS Number: 657-27-2 <i>Analytical methods</i> ⁽¹⁾: For the identification of L-lysine monohydrochloride in the feed additive:	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive.	16 May 2031

			— Food Chemical Codex 'L-lysine monohydrochloride monograph' For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F).				2. L-lysine monohydrochloride, technically pure, may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation and eye contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection and safety glasses.	
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

⁽²⁾ Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (*EFSA Journal* 2017;15(3):4705); analytical method: European Pharmacopoeia 2.6.14 (bacterial endotoxins).

COMMISSION IMPLEMENTING REGULATION (EU) 2021/670

of 23 April 2021

authorising the placing on the market of *Schizochytrium* sp. (WZU477) oil as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) On 14 March 2019, the company Progress Biotech bv ('the applicant') submitted an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 for an extension of use of the novel food *Schizochytrium* sp. oil. The application requested to extend the use of *Schizochytrium* sp. oil to infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽³⁾ intended for infants and young children. The strain of *Schizochytrium* sp. used by the applicant and concerned by this application is specified as strain WZU477.
- (4) The applicant also submitted a request to the Commission for the protection of proprietary data for a number of original data submitted in support of its application, being data submitted in support of the initial application of 14 March 2019 namely, application 2012 ⁽⁴⁾; detailed description of the production process ⁽⁵⁾; chemical characteristics ⁽⁶⁾; fatty acid analysis ⁽⁷⁾; sterol analysis ⁽⁸⁾; heavy metals analysis ⁽⁹⁾; PAH analysis ⁽¹⁰⁾; mycotoxin analysis ⁽¹¹⁾; dioxin, dioxin like, PCB, pesticides analysis ⁽¹²⁾; microbiological analysis ⁽¹³⁾; retrospective stability

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

⁽⁴⁾ Annex I (NF application 2012), Progress Biotech bv, 2012 (unpublished).

⁽⁵⁾ Detailed description of the production process, Progress Biotech bv, 2019 (unpublished).

⁽⁶⁾ Annex II (chemical characteristics), Progress Biotech bv, 2019 (unpublished).

⁽⁷⁾ Annex III (fatty acid analysis), Progress Biotech bv, 2019 (unpublished).

⁽⁸⁾ Annex IV (sterol analysis), Progress Biotech bv, 2019 (unpublished).

⁽⁹⁾ Annex V (heavy metals analysis), Progress Biotech bv, 2019 (unpublished).

⁽¹⁰⁾ Annex VI (PAH analysis), Progress Biotech bv, 2019 (unpublished).

⁽¹¹⁾ Annex VII (mycotoxin analysis), Progress Biotech bv, 2019 (unpublished).

⁽¹²⁾ Annex VIII (dioxin, dioxin like, PCB, pesticides analysis), Progress Biotech bv, 2019 (unpublished).

⁽¹³⁾ Annex IX (microbiological analysis), Progress Biotech bv, 2019 (unpublished).

study ⁽¹⁴⁾; analytical lab certificates ⁽¹⁵⁾; compositional data ⁽¹⁶⁾. The applicant also requested data protection for the additional data submitted in the course of the safety assessment carried out by the Authority: protein analysis ⁽¹⁷⁾; 3 MCPD & glycidyl ester analyses ⁽¹⁸⁾; physicochemical analysis ⁽¹⁹⁾; microbiological analysis ⁽²⁰⁾; heavy metals analysis ⁽²¹⁾; mycotoxin analysis ⁽²²⁾; PAH, dioxin and dioxin-like contaminants analysis ⁽²³⁾; fatty acid profile analysis ⁽²⁴⁾; sterol composition analysis ⁽²⁵⁾; hydrolytic rancidity analysis over time ⁽²⁶⁾; marine biotoxin analysis ⁽²⁷⁾; stability study ⁽²⁸⁾; certificate of analysis ⁽²⁹⁾.

- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 24 June 2019, requesting it to provide a scientific opinion by carrying out an assessment for an extension of use of *Schizochytrium* sp. oil as a novel food in infant formula and follow-on formula.
- (6) On 31 August 2020, the Authority adopted its scientific opinion on the "Safety of *Schizochytrium* sp. oil as a novel food pursuant to Regulation (EU) 2015/2283" ⁽³⁰⁾. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (7) In that opinion, the Authority confirmed that the identity of the strain WZU477 belongs to the species *Schizochytrium limacinum*, which was attributed the qualified presumption of safety ('QPS') status and included in 2020 in the list of QPS-recommended biological agents intentionally added to food or feed ⁽³¹⁾. In its opinion, the Authority concluded that *Schizochytrium* sp. oil produced from the strain WZU477 belonging to species *Schizochytrium limacinum* is safe under the proposed conditions of use. Data submitted by the applicant did not allow for a conclusion on the safety of oil produced from other strains of the *Schizochytrium* microalgae genus. The opinion of the Authority gives sufficient grounds to establish that *Schizochytrium* sp. (WZU477) oil under the proposed uses and use levels complies with the requirements of Article 12(1) of Regulation (EU) 2015/2283.
- (8) Therefore, the opinion of the Authority does not give sufficient grounds to establish that oil produced from other strains of the *Schizochytrium* microalgae genus when used in infant formula and follow on formula, complies with Article 12(1) of Regulation (EU) 2015/2283. Following the Authority's opinion and taking into account that the authorised *Schizochytrium* sp. oil for which an extension of use was requested is neither species-specific nor strain-specific, it is therefore necessary to authorise the placing on the market of oil from strain WZU477 of *Schizochytrium* sp., and not an extension of use of oil from all strains of the *Schizochytrium* genus as requested by the applicant.

⁽¹⁴⁾ Annex XI (retrospective stability study), Progress Biotech bv, 2019 (unpublished).

⁽¹⁵⁾ Annex XII (analytical lab certificates), (unpublished).

⁽¹⁶⁾ Appendix B.2 (compositional data), Progress Biotech bv, 2019 (unpublished).

⁽¹⁷⁾ Annex IV (protein analysis), Progress Biotech bv, 2020 (unpublished).

⁽¹⁸⁾ Annex VI (3 MCPD & glycidyl ester analyses), Progress Biotech bv, 2020 (unpublished).

⁽¹⁹⁾ Annex VII (physicochemical analysis), Progress Biotech bv, 2020 (unpublished).

⁽²⁰⁾ Annex VIII (microbiological analysis), Progress Biotech bv, 2020 (unpublished).

⁽²¹⁾ Annex IX (heavy metals analysis), Progress Biotech bv, 2020 (unpublished).

⁽²²⁾ Annex X (mycotoxin analysis), Progress Biotech bv, 2019 (unpublished).

⁽²³⁾ Annex XI (PAH, dioxin and dioxin-like contaminants analysis), Progress Biotech bv, 2020 (unpublished).

⁽²⁴⁾ Annex XII (fatty acid profile analysis), Progress Biotech bv, 2020 (unpublished).

⁽²⁵⁾ Annex XIV (sterol composition analysis), Progress Biotech bv, 2020 (unpublished).

⁽²⁶⁾ Annex XVII (hydrolytic rancidity analysis over time), Progress Biotech bv, 2020 (unpublished).

⁽²⁷⁾ Annex 1 (marine biotoxin analysis), Wageningen Food Safety Research Lab, 2020 (unpublished).

⁽²⁸⁾ Annex 3 (stability study), Progress Biotech bv, 2018 (unpublished).

⁽²⁹⁾ Annex I (certificate of analysis), Progress Biotech bv, 2016 (unpublished).

⁽³⁰⁾ EFSA Journal 2020;18(10):6242.

⁽³¹⁾ EFSA BIOHAZ Panel, 2020. Statement on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 11: suitability of taxonomic units notified to EFSA until September 2019. EFSA Journal 2020;18(2):5965, 57 pp.

- (9) In its opinion, the Authority considered that the data from the application 2012, detailed description of the production process, chemical characteristics, fatty acid analysis, sterol analysis, heavy metals analysis, PAH analysis, mycotoxin analysis, dioxin, dioxin like, PCB, pesticides analysis, microbiological analysis, retrospective stability study, analytical lab certificates, compositional data, 3 MCPD & glycidyl ester analyses, physicochemical analysis, microbiological analysis, heavy metals analysis, mycotoxin analysis, PAH, dioxin and dioxin-like contaminants analysis, fatty acid profile analysis, sterol composition analysis, hydrolytic rancidity analysis over time, marine biotoxin analysis, stability study and certificate of analysis served as a basis to establish the safety of the novel food. On this basis, the Commission considers that the conclusions on the safety of *Schizochytrium* sp. (WZU477) oil could not have been reached without the data from the reports of those studies.
- (10) Following the authority's opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the application 2012, detailed description of the production process, chemical characteristics, fatty acid analysis, sterol analysis, heavy metals analysis, PAH analysis, mycotoxin analysis, dioxin, dioxin like, PCB, pesticides analysis, microbiological analysis, retrospective stability study, analytical lab certificates, compositional data, 3 MCPD & glycidyl ester analyses, physicochemical analysis, microbiological analysis, heavy metals analysis, mycotoxin analysis, PAH, dioxin and dioxin-like contaminants analysis, fatty acid profile analysis, sterol composition analysis, hydrolytic rancidity analysis over time, marine biotoxin analysis, stability study and certificate of analysis, and to clarify their claim to an exclusive right of reference to that data, as required under Article 26(2)(b) of Regulation (EU) 2015/2283.
- (11) The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive rights of reference to that data under national law, and that therefore third parties cannot lawfully access or use those studies or refer to that data.
- (12) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the application 2012, detailed description of the production process, chemical characteristics, fatty acid analysis, sterol analysis, heavy metals analysis, PAH analysis, mycotoxin analysis, dioxin, dioxin like, PCB, pesticides analysis, microbiological analysis, retrospective stability study, analytical lab certificates, compositional data, 3 MCPD & glycidyl ester analyses, physicochemical analysis, microbiological analysis, heavy metals analysis, mycotoxin analysis, PAH, dioxin and dioxin-like contaminants analysis, fatty acid profile analysis, sterol composition analysis, hydrolytic rancidity analysis over time, marine biotoxin analysis, stability study and certificate of analysis contained in the applicant's file should not be used by the Authority for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of *Schizochytrium* sp. (WZU477) oil should be restricted to the applicant for that period.
- (13) However, restricting the authorisation of *Schizochytrium* sp. (WZU477) oil and of the reference to the data contained in the applicant's file for the sole use of the applicant, does not prevent other applicants from applying for an authorisation to place on the market the same novel food, provided that their application is based on legally obtained information supporting such authorisation under Regulation (EU) 2015/2283.
- (14) Implementing Regulation (EU) 2017/2470 should be therefore amended accordingly.
- (15) 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

1. *Schizochytrium* sp. (WZU477) oil as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of five years from the date of entry into force of this Regulation only the initial applicant:

— Company: Progress Biotech bv,

— Address: Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den IJssel, the Netherlands,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for that novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Progress Biotech bv.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

Article 2

The data contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation, without the agreement of Progress Biotech bv.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 4

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

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

Done at Brussels, 23 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'Schizochytrium sp. (WZU477) oil	<i>Specified food category</i>	<i>Maximum levels of DHA</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Oil from the microalgae <i>Schizochytrium</i> sp."		Authorised on 16 May 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Progress Biotech bv, Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den IJssel, the Netherlands. During the period of data protection, the novel food is authorised for placing on the market within the Union only by Progress Biotech bv unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Progress Biotech bv. End date of the data protection: 16 May 2026 (5 years).'
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specification
'Schizochytrium sp. (WZU477) oil	Description/Definition: The novel food is an oil produced from the strain WZU477 of the microalgae <i>Schizochytrium</i> sp. Composition: Acid value: $\leq 0,5$ mg KOH/g Peroxide value (PV): $\leq 5,0$ meq/kg oil Moisture and volatiles: $\leq 0,05$ % Unsaponifiables: $\leq 4,5$ % Trans-fatty acids: $\leq 1,0$ % Docosahexaenoic acid (DHA): $\geq 32,0$ % p-anisidine value: ≤ 10

DECISIONS

COUNCIL DECISION (EU) 2021/671

of 20 April 2021

on the position to be taken on behalf of the European Union in the written procedure by the Participants to the Arrangement on Officially Supported Export Credits as regards the adoption of a decision to increase official support for export credits in the form of local costs

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 207(4), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The guidelines contained in the Arrangement on Officially Supported Export Credits (the 'Arrangement') apply in the Union by virtue of Regulation (EU) No 1233/2011 of the European Parliament and of the Council ⁽¹⁾.
- (2) The 145th session of the Meeting of the Participants to the Arrangement, that took place on 17 November 2020, agreed to adopt in a written procedure a decision to amend the Arrangement to increase official support for export credits in the form of local costs.
- (3) The envisaged decision to increase official support for local costs should adapt the provisions on local cost support in the Arrangement to prevailing trade and production patterns. Global value chains have changed exporters' sourcing decisions and most exporters now source supply from multiple countries and to an increasing extent from where the buyer is located. In order to offer Union exporters greater flexibility and to allow for optimal sourcing strategies the cap on official support for local costs should be raised from 30 % to 40 % of the export contract value in high-income countries and from 30 % to 50 % of the export contract value in middle- and low-income countries.
- (4) It is appropriate to establish the position to be taken on the Union's behalf on the decision to be adopted by the Participants to the Arrangement in the written procedure, as the envisaged decision will be capable of decisively influencing the content of Union law, by virtue of Article 2 of Regulation (EU) No 1233/2011,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf in the written procedure by the Participants to the Arrangement on Officially Supported Export Credits as regards the adoption of a decision to increase official support for export credits in the form of local costs shall be based on the proposal of the Union ⁽²⁾.

Article 2

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

⁽¹⁾ Regulation (EU) No 1233/2011 of the European Parliament and of the Council of 16 November 2011 on the application of certain guidelines in the field of officially supported export credits and repealing Council Decisions 2001/76/EC and 2001/77/EC (OJ L 326, 8.12.2011, p. 45).

⁽²⁾ See document ST 7202/21 on <http://register.consilium.europa.eu>

Done at Brussels, 20 April 2021.

For the Council
The President
A. P. ZACARIAS

COUNCIL IMPLEMENTING DECISION (CFSP) 2021/672**of 23 April 2021****implementing Decision (CFSP) 2015/1333 concerning restrictive measures in view of the situation in Libya**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 31(2) thereof,

Having regard to Council Decision (CFSP) 2015/1333 of 31 July 2015 concerning restrictive measures in view of the situation in Libya, and repealing Decision 2011/137/CFSP ⁽¹⁾, and in particular Article 12(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 31 July 2015, the Council adopted Decision (CFSP) 2015/1333 concerning restrictive measures in view of the situation in Libya.
- (2) The entry for one person should be deleted as he is deceased.
- (3) Annexes II and IV to Decision (CFSP) 2015/1333 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annexes II and IV to Decision (CFSP) 2015/1333 are amended in accordance with the Annex to this Decision.

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, 23 April 2021.

For the Council

The President

A. P. ZACARIAS

⁽¹⁾ OJ L 206, 1.8.2015, p. 34.

ANNEX

Decision (CFSP) 2015/1333 is amended as follows:

- (1) in Annex II (List of persons and entities referred to in Article 8(2)), Part A (Persons), entry 10 (concerning AL-GAOUD, Abdelmajid) is deleted;
 - (2) in Annex IV (List of persons and entities referred to in Article 9(2)), Part A (Persons), entry 10 (concerning AL-GAOUD, Abdelmajid) is deleted.
-

COMMISSION IMPLEMENTING DECISION (EU) 2021/673**of 21 April 2021****on the request for registration of the European citizens' initiative entitled 'Green Garden Roof Tops'***(notified under document C(2021) 2750)***(Only the English text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/788 of the European Parliament and of the Council of 17 April 2019 on the European citizens' initiative ⁽¹⁾, and in particular Article 6(2) and (3) thereof,

Whereas:

- (1) A request for registration of a European citizens' initiative entitled 'Green Garden Roof Tops' was submitted to the Commission on 3 March 2021.
- (2) The objectives of the initiative are expressed as follows: 'In Europe there are many existing stores with an empty rooftop; in most of the cases these rooftops are not being used for any specific purpose. In addition, these rooftops are full of plastic and stones, materials of which the roof is made of. Therefore, these areas are in itself not contributing to the benefits of the environment, rather they are simply increasing the environmental damages. The reason of focusing on the environmental benefits is stemming from our current time environmental crisis. We need to rethink and find ways to increase the awareness of environmental problems and how to bring our society, the economy and the protection of our planet in a healthy balance. Therefore, the core of the plan is to utilize the existing spaces found on rooftops. The idea is to create on different corporations' rooftops a green garden area. In this way the unutilized roofs, could be transformed in means able of improving and aiding the environmental crisis.'
- (3) A background document provides further details on the initiative. In particular, the initiative proposes that employees of the corporations could volunteer to take part in the maintenance of the rooftop gardens and Member States could encourage companies to take an active part in the projects by providing tax credits at the end of each fiscal year. The annex also lists the perceived benefits for the environment and the corporations themselves. The garden rooftops would (1) contribute to improving air quality; (2) contribute to fight climate change; (3) lead to energy savings; (4) improve water filtration and retention and (5) contribute to wildlife habitat. Corporations concerned would benefit in terms of contributing to a good reputation, motivated staff and tax benefits.
- (4) The organisers do not explicitly invite the Commission to adopt a specific legal act, but the envisaged act can be inferred from some of the proposed legal bases for action. From the objectives, read together with the annex, it can be concluded that the initiative is asking for the adoption of a proposal for a legal act which would pursue an environmental objective with a taxation component. The voluntary contribution of the workers would appear to be ancillary to the environmental objective.
- (5) Insofar as the initiative aims to promote the creation of green rooftops with possible financing incentives from the Union or measures of fiscal nature, the Commission has the power to adopt a legal act under Article 192 of the Treaty.
- (6) Insofar as the proposed initiative aims to promote tax credits or deductions from income tax to be granted by the Member States, the Commission has the power to adopt a legal act under Article 115 of the Treaty.

⁽¹⁾ OJ L 130, 17.5.2019, p. 55.

- (7) For these reasons, none of the parts of the initiative manifestly falls outside the framework of the Commission's powers to submit a proposal for a legal act of the Union for the purpose of implementing the Treaties.
- (8) The group of organisers has provided appropriate evidence that it fulfils the requirements laid down in Article 5(1) and (2) of Regulation (EU) 2019/788 and has designated the contact persons in accordance with Article 5(3), first subparagraph, of that Regulation.
- (9) The initiative is not manifestly abusive, frivolous or vexatious, nor is it manifestly contrary to the values of the Union as set out in Article 2 of the Treaty on European Union and rights enshrined in the Charter of Fundamental Rights of the European Union.
- (10) The initiative entitled 'Green Garden Roof Tops' should therefore be registered,

HAS ADOPTED THIS DECISION:

Article 1

The European citizens' initiative entitled 'Green Garden Roof Tops' shall be registered.

Article 2

This Decision is addressed to the group of organisers of the European citizens' initiative entitled 'Green Garden Roof Tops', represented by Ms Almog Yoana SADE and Mr Negev Raphael SADE acting as contact persons.

Done at Brussels, 21 April 2021.

For the Commission
Věra JOUROVÁ
Vice-President

COMMISSION IMPLEMENTING DECISION (EU) 2021/674**of 21 April 2021****on the request for registration of the European citizens' initiative entitled 'Civil Servant Exchange Program (CSEP)'***(notified under document C(2021) 2784)***(Only the English text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/788 of the European Parliament and of the Council of 17 April 2019 on the European citizens' initiative ⁽¹⁾, and in particular Article 6(2) and (3) thereof,

Whereas:

- (1) A request for registration of the European citizens' initiative entitled 'Civil Servant Exchange Program (CSEP)' was submitted to the Commission on 27 February 2021.
- (2) The objectives of the initiative are expressed as follows: 'As European students and future civil servants, we believe that exchanges should not stop once studies come to an end. We therefore propose the creation of a Civil Servant Exchange Program (CSEP), an exchange and training programme between civil servants of the Member States of the European Union. The aim of this 'Erasmus for the civil service' would be to offer civil servants from EU Member States professional experience in a similar service in another Member State for a period of 2 to 12 months. During the exchange, civil servants could continue to receive the salary of their home country, subject to compensation from the EU if this salary is lower than that received in the host country for an equivalent position. The CSEP would strengthen the freedom of movement of workers in the EU, foster an exchange of best practices between civil services and improve links between Member States. In addition, the CSEP would help civil servants to overcome the numerous challenges they encounter in their working relations with their European colleagues. The CSEP would initiate a new spirit of unity, by citizens and for citizens, thanks to civil servants from European countries.'
- (3) An annex provides further details on the subject matter, objectives and background to the initiative. In particular, it sets out the perceived advantages of the programme, namely the benefits of a European experience, the development of additional skills and exchange of best practices and the strengthening of the EU and its Member States. The annex indicates that the programme should benefit many categories of civil servants, such as teachers, public health staff, and staff in criminal, judicial and administrative functions. It also addresses the remuneration of officials participating in the exchanges and the Union financial contribution.
- (4) The initiative proposes the creation of an exchange programme in the form of a legislative framework allowing Member States to voluntarily assign positions in their administration to be made available to civil servants from other Member States for the purpose of an exchange, while respecting the principle of subsidiarity and the respective competences of the EU and the Member States' and the possibility to limit access to some positions in order to maintain public order and safeguard the security of important national public information.
- (5) Insofar as the programme aims at developing exchanges of information and best practices between civil servants, the Commission has the power to propose it as an incentive measure designed to encourage cooperation between Member States and to support their action in the field of employment on the basis of Article 149 of the Treaty.
- (6) Moreover, the programme could also be proposed on the basis of Article 165(4) and Article 166(4) of the Treaty, insofar as it aims at encouraging mobility of teachers and instructors and developing education and vocational training.

⁽¹⁾ OJ L 130, 17.5.2019, p. 55.

- (7) Finally, the programme could be proposed on the basis of Article 197(2) of the Treaty, insofar as it would aim to improve the administrative capacity of Member States to implement Union law.
- (8) For these reasons, none of the parts of the proposed initiative manifestly falls outside the framework of the Commission's powers to submit a proposal for a legal act of the Union for the purpose of implementing the Treaties.
- (9) The group of organisers has provided appropriate evidence that it fulfils the requirements laid down in Article 5(1) and (2) of Regulation (EU) 2019/788 and has designated the contact persons in accordance with Article 5(3), first subparagraph, of that Regulation.
- (10) The initiative is not manifestly abusive, frivolous or vexatious, nor is it manifestly contrary to the values of the Union as set out in Article 2 of the Treaty on European Union and rights enshrined in the Charter of Fundamental Rights of the European Union.
- (11) The initiative entitled 'Civil Servant Exchange Program (CSEP)' should therefore be registered,

HAS ADOPTED THIS DECISION:

Article 1

The European citizens' initiative entitled 'Civil Servant Exchange Program (CSEP)' shall be registered.

Article 2

This Decision is addressed to the group of organisers of the European citizens' initiative entitled 'Civil Servant Exchange Program (CSEP)', represented by Mr Johan GONCALVES and Mr Adam MAZOYER acting as contact persons.

Done at Brussels, 21 April 2021.

For the Commission
Věra JOUROVÁ
Vice-President

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