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Contents

[1] Text with EEA relevance.

EN

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

The titles of all other acts are printed in bold type and preceded by an asterisk.

[1] Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2021/77

of 27 January 2021

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([1]), and in particular Article 18(5) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.

(3) The Authority is to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims, taking into account the opinion delivered by the Authority.

(5) Following an application from Lonza Ltd, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to L-carnitine and normal lipid metabolism (Question No EFSA- Q-2017-00564). The claim proposed by the applicant was worded as follows: 'L-carnitine contributes to normal lipid metabolism'.

(6) On 16 January 2018, the Commission and the Member States received the scientific opinion ([2]) from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship has not been established between the consumption of L-carnitine and contribution to normal lipid metabolism in the target population. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) EFSA Journal 2018;16(1):5137.

(7) Following an application from Unilever N.V., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to black tea and maintenance of normal endothelium-dependent vasodilation (Question No EFSA-Q-2017-00419). The claim proposed by the applicant was worded as follows: 'improves endothelium-dependent vasodilation which contributes to healthy blood flow'.

(8) On 16 January 2018, the Commission and the Member States received the scientific opinion ([3]) from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship has not been established between the consumption of black tea and maintenance of normal endothelium-dependent vasodilation. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) Following an application from Newtricious R & D B.V., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to NWT-02, a fixed combination of lutein, zeaxanthin and docosahexaenoic acid in egg yolk, and a reduction of the loss of vision (Question No EFSA-Q-2017-00539). The claim proposed by the applicant was worded as follows: 'Consumption of NWT-02 reduces loss of vision'.

(10) On 18 January 2018, the Commission and the Member States received the scientific opinion ([4]) from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship has not been established between the consumption of NWT-02, a fixed combination of lutein, zeaxanthin and DHA in egg yolk and a reduction of the loss of vision. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) Following an application from TA-XAN AG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to xanthohumol in XERME®, a xanthohumol-enriched roasted malt extract, and protection of DNA from oxidative damage (Question No EFSA-Q-2017-00663). The claim proposed by the applicant was worded as follows: 'helps to maintain the integrity of DNA and protects against oxidative damage in the cells of the body'.

(12) On 13 March 2018, the Commission and the Member States received the scientific opinion ([5]) from the Authority which concluded that, on the basis of the data presented, a cause and effect relationship has not been established between the consumption of xanthohumol in XERME®, a xanthohumol-enriched roasted malt extract, and protection of DNA from oxidative damage. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(13) Following an application from Essential Sterolin Products (Pty) Ltd., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to a combination of beta-sitosterol and beta-sitosterol glucoside and normal function of the immune system (Question No EFSA-Q-2018-00701). The claim proposed by the applicant was worded as follows: 'contributes to the normal function of the immune system by restoring balance between T_H1- and T_H2- mediated immunity'.

(14) On 24 July 2019, the Commission and the Member States received the scientific opinion ([6]) from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship cannot be established between the consumption of a combination of beta-sitosterol and beta-sitosterol glucoside in a ratio 100:1 and a beneficial physiological effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([3]) EFSA Journal 2018;16(1):5138.
([4]) EFSA Journal 2018;16(1):5139.
([5]) EFSA Journal 2018;16(3):5192.
([6]) EFSA Journal 2019;17(7):5776.

HAS ADOPTED THIS REGULATION:

Article 1

The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

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, 27 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Rejected health claims

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	L-carnitine	L-carnitine contributes to normal lipid metabolism.	2018;16(1):5137
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Black tea	Improves endothelium-dependent vasodilation, which contributes to healthy blood flow.	2018;16(1):5138
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	NWT-02, a fixed combination of lutein, zeaxanthin and docosahexaenoic acid in egg yolk.	Consumption of NWT-02 reduces loss of vision.	2018;16(1):5139
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Xanthohumol in XERME®, a xanthohumol-enriched roasted malt extract.	Helps to maintain the integrity of DNA and protects against oxidative damage in the cells of the body.	2018;16(3):5192
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A combination of beta-sitosterol and beta-sitosterol glucoside	Contributes to the normal function of the immune system by restoring balance between T_H1- and T_H2- mediated immunity.	2019;17(7):5776

COMMISSION IMPLEMENTING REGULATION (EU) 2021/78

of 27 January 2021

amending Implementing Regulation (EU) 2020/600 derogating from Implementing Regulation (EU) 2017/892, Implementing Regulation (EU) 2016/1150, Implementing Regulation (EU) No 615/2014, Implementing Regulation (EU) 2015/1368 and Implementing Regulation (EU) 2017/39 as regards certain measures to address the crisis caused by the COVID-19 pandemic

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 54 thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2020/600 ([2]) introduced a number of derogations from existing rules, inter alia, in the wine sector, aimed at providing relief to wine operators to help them cope with the impact of the COVID-19 pandemic. However, despite the usefulness of those measures, the wine market has not managed to regain its balance between supply and demand and is not expected to regain it in the short to medium term due to the ongoing pandemic.

(2) Furthermore, the measures adopted to address the COVID-19 pandemic are being continued in most Member States and across the world. Those measures include imposing restrictions in relation to the size of social gatherings and celebrations, and in relation to the possibilities to eat and drink outside the home. Lockdowns continue to be imposed in some areas, accompanied by the cancellation of public events and private parties. The knock-on effect of these restrictions has resulted in a further decrease in the consumption of wine in the Union and in a confirmed reduction in the export of wine to third countries. In addition, the uncertainty as to the duration of the crisis, which it is anticipated will likely extend beyond the end of the year 2020, is causing long-term damage to the Union wine sector as wine consumption is unlikely to recover and export markets will be lost. This combination of factors is having a significant negative impact on pricing in the Union wine market. Stocks that were already at a record high at the beginning of the marketing year 2019-2020 have been increased. Finally, the upcoming high-yielding 2020 harvest, which is expected to exceed the 2019 harvest by approximately 10 million hectolitres of wine, will only serve to further worsen the situation.

(3) Consequently, given the lengthy duration of the restrictions imposed by Member States to address the COVID-19 pandemic and the need to keep restrictions in place, the severe economic disruption to the main outlets for wine and the ensuing negative effect on the demand for wine are exacerbated.

(4) In light of this exceptionally severe market disturbance and of the accumulation of difficult circumstances encountered in the wine sector, which has its origin in the imposition by the United States of tariffs on the imports of Union wines in October 2019 and which continues now with the fall-out from the on-going restrictive measures due to the worldwide COVID-19 pandemic, exceptional difficulties continue to be encountered by operators in the Union wine sector. Further assistance to the wine sector is therefore warranted.

(5) The continued implementation of the measures to address the crisis in the Union wine sector which were introduced by Implementing Regulation (EU) 2020/600 is considered essential to provide Member States and operators with the necessary flexibilities to implement support programmes in the Union wine sector. In particular, the possibility for Member States to introduce changes to their respective national programmes whenever necessary during the year

([1]) OJ L 347, 20.12.2013, p. 671.

([2]) Commission Implementing Regulation (EU) 2020/600 of 30 April 2020 derogating from Implementing Regulation (EU) 2017/892, Implementing Regulation (EU) 2016/1150, Implementing Regulation (EU) No 615/2014, Implementing Regulation (EU) 2015/1368 and Implementing Regulation (EU) 2017/39 as regards certain measures to address the crisis caused by the COVID-19 pandemic (OJ L 140, 4.5.2020, p. 40).

has enabled Member States to react quickly to the exceptional circumstances of the recent months and to submit changes to their support programmes as early as deemed necessary. This flexibility has allowed Member States to introduce new measures, optimise measures already in place and to adjust measures more frequently, and as necessary, taking account of the fast changing market situation. In addition, the flexibility introduced for the implementation of the green harvesting measure has afforded operators the time required to plan the measure and to find the requisite labour force to operate under the difficult conditions arising from the COVID-19 pandemic.

(6) As the COVID-19 pandemic is expected to continue beyond the end of the year 2020 and thus during a considerable part of the financial year 2021, it is considered necessary to extend the application of the measures for the duration of the financial year 2021.

(7) In addition, due to the difficulties encountered in the management of the national support programmes during the ongoing COVID-19 pandemic, some Member States have reported that they are not in a position to re-examine the standard scales of unit costs applied to certain measures in those programmes and established pursuant to Article 24(1) of Commission Implementing Regulation (EU) 2016/1150 ([3]). Therefore, during the years 2020, 2021 and 2022, Member States should have the possibility to extend the period during which such re-examination shall be carried out, from every second year following the last calculations, as provided for in Article 24(3) of that Regulation, to the fourth year following the last calculations. To avoid discrimination, this flexibility should apply retroactively as of the date of entry into force of Implementing Regulation (EU) 2020/600.

(8) Implementing Regulation (EU) 2020/600 should therefore be amended accordingly.

(9) In order to avoid disruption in the implementation of the measures to address the crisis in the Union wine sector and ensure a smooth transition between the two financial years, this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union* and apply retroactively from 16 October 2020.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2020/600

Article 2 of Implementing Regulation (EU) 2020/600 is amended as follows:

(1) paragraph 1 is replaced by the following:

‘1. By way of derogation from Article 2(1) of Implementing Regulation (EU) 2016/1150, Member States may introduce, in relation to the measures referred to in Articles 45(1)(a) and 46 to 52 of Regulation (EU) No 1308/2013, whenever necessary during the financial years 2020 and 2021 but not later than 15 October 2021, changes to their national support programmes in the wine sector as referred to in Article 41(5) of Regulation (EU) No 1308/2013.’;

(2) in paragraph 2, the introductory phrase is replaced by the following:

‘2. By way of derogation from Article 8 of Implementing Regulation (EU) 2016/1150, during the financial years 2020 and 2021, Member States may:’;

([3]) Commission Implementing Regulation (EU) 2016/1150 of 15 April 2016 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the national support programmes in the wine sector (OJ L 190, 15.7.2016, p. 23).

(3) the following paragraph 3 is added:

'3. By way of derogation from Article 24(3) of Implementing Regulation (EU) 2016/1150, during the years 2020, 2021 and 2022, Member States shall re-examine the calculations provided for in paragraph 1 of that Article at the latest in the fourth year following the previous calculations and shall, if necessary, adjust the initially established standard scales of unit costs.'.

Article 2

Entry into force and application

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

It shall apply from 16 October 2020. However, point (3) of Article 1 shall apply as of 4 May 2020.

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

Done at Brussels, 27 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/79

of 27 January 2021

concerning the non-approval of the active substance topramezone, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 13(2) thereof,

Whereas:

(1) According to Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ([2]) applies to the procedure and the conditions for approval of active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive, before 14 June 2011. On 9 December 2003, the Commission adopted Decision 2003/850/EC ([3]) on the active substance topramezone (formerly BAS 670H) in accordance with Article 6(3) of Directive 91/414/EEC.

(2) On 12 May 2003, BASF Aktiengesellschaft (now BASF SE) submitted an application for the inclusion of topramezone in Annex I to Directive 91/414/EEC to France in accordance with Article 6(2) of that Directive. Decision 2003/850/EC confirmed that the dossier satisfied, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) The assessment of the effects of topramezone on human and animal health and the environment for the uses proposed by the applicant has been carried out in accordance with the procedure provided in Article 6(2) and (4) of Directive 91/414/EEC. France submitted a draft assessment report to the Commission and the European Food Safety Authority ('the Authority') on 21 July 2006.

(4) The draft assessment report was reviewed by the Member States and the Authority. The Authority presented to the Commission its conclusion ([4]) on the pesticide risk assessment of the active substance topramezone on 13 January 2014.

(5) By letter of 29 June 2020, BASF SE withdrew the application for the approval of topramezone.

(6) Due to the withdrawal of the application, topramezone should not be approved.

(7) This Regulation does not prevent the submission of a further application for the active substance topramezone pursuant to Article 7 of Regulation (EC) No 1107/2009.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([3]) Commission Decision 2003/850/EC of 4 December 2003 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of BAS 670H and silver thiosulphate in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 322, 9.12.2003, p. 28).

([4]) European Food Safety Authority, 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance topramezone. *EFSA Journal* 2014;12(2):3540, 82 pp. doi:10.2903/j.efsa.2014.3540.

HAS ADOPTED THIS REGULATION:

Article 1

Non-approval of active substance

The active substance topramezone is not approved.

Article 2

Entry into force

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

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

Done at Brussels, 27 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/80

of 27 January 2021

concerning the non-approval of carbon dioxide as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market ([1]), and in particular Article 23(5) in conjunction with Article 13(2)

Whereas:

(1) On 27 February 2018, the Commission received an application from Dr Knoell Consult GmbH for the approval of food grade carbon dioxide (E 290) as a basic substance (CAS No 124-38-9). The application referred to a use as post-harvest fumigant against insects and mites.

(2) Carbon dioxide is already approved as an active substance for use in plant protection products since 1 September 2009 ([2]) and is included in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]).

(3) Carbon dioxide is currently authorised and placed on the market as a plant protection product in several Member States. The specification of the substance identity in the application for approval as a basic substance is identical to that of the approved active substance.

(4) Although the third subparagraph provides that foodstuff is to be considered as a basic substance, Article 23(1)(d) of Regulation (EC) No 1107/2009 excludes the approval of food-grade carbon dioxide, because a substance can, among other criteria, be only approved as a basic substance if it is not placed on the market as a plant protection product. This is, however, currently the case for food-grade carbon dioxide.

(5) This Regulation is without prejudice to the submission of a new application for the approval of carbon dioxide as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009 once the existing approval of carbon dioxide as an active substance has expired and once all authorisations for plant protection products consisting of carbon dioxide have been withdrawn or have expired.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The substance carbon dioxide (E 290) is not approved as a basic substance.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).

([3]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

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, 27 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/81

of 27 January 2021

approving the basic substance Allium cepa L. bulb extract in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 23(5) in conjunction with Article 13(2) thereof,

Whereas:

(1) On 4 September 2018, the Commission received an application from l'Institut de l'agriculture et de l'alimentation Biologique (ITAB), for the approval of *Allium cepa* L. bulb extract as a basic substance. That application was accompanied by the information required by the second subparagraph of Article 23(3) of Regulation (EC) No 1107/2009.

(2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance. The Authority provided the Commission with a technical report on *Allium cepa* L. bulb extract on 12 December 2019 ([2]). The Commission presented the review report ([3]) and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 18 May 2020.

(3) The information provided by the applicant shows that the *Allium cepa* L. bulb extract fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([4]). Moreover, it is not predominantly used for plant protection purposes but the extract can be useful in plant protection in a product consisting of the substance. Consequently, it is to be considered as a basic substance.

(4) After examination of the application and all related documents, it may be expected that the *Allium cepa* L. bulb extract satisfies, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve the *Allium cepa* L. bulb extract as a basic substance.

(5) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions for the approval.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) EFSA (European Food Safety Authority), 2019. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for *Allium cepa* bulb extract for use in plant protection as a fungicide in potatoes, tomatoes and cucumbers. EFSA supporting publication 2019:EN-1767. doi:10.2903/sp.efsa.2019.EN-1767.

([3]) Final Review report for the basic substance *Allium cepa* L. bulb extract finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 22 October 2020 in view of the approval of *Allium cepa* L. bulb extract as basic substance in accordance with Regulation (EC) No 1107/2009 (SANTE/10842/2020 Rev2).

([4]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

(6) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ([5]) should be amended accordingly.

(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

Approval of a basic substance

The substance *Allium cepa* L. bulb extract as specified in Annex I is approved as a basic substance subject to the conditions as laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

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

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

Done at Brussels, 27 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

([5]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ([1])	Date of approval	Specific provisions
Allium cepa L. bulb extract CAS No: not allocated CIPAC No: not allocated	Not applicable	The onion bulbs used to prepare the extracts shall be of food grade quality meeting the requirements of WHO monographs on selected medicinal plants (Volume 1, Geneva, 1999) on Bulbus *Allii Cepae*	17.2.2021	*Allium cepa* L. bulb extract shall be used in accordance with the specific conditions included in the conclusions of the review report on *Allium cepa* L. bulb extract (SANTE/10842/2020 Rev2) and in particular Appendices I and II thereof.

([1]) Further details on identity, specification and manner of use of the basic substance are provided in the review report.

ANNEX II

In Part C of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Specific provisions
'23	*Allium cepa* L. bulb extract CAS No: not allocated CIPAC No: not allocated	Not applicable	The onion bulbs used to prepare the extracts shall be of food grade quality meeting the requirements of WHO monographs on selected medicinal plants (Volume 1, Geneva, 1999) on Bulbus *Allii Cepae*	17.2.2021	*Allium cepa* L. bulb extract shall be used in accordance with the specific conditions included in the conclusions of the review report on *Allium cepa* L. bulb extract (SANTE/10842/2020 Rev2) and in particular Appendices I and II thereof.'

[1] Further details on identity, specification and manner of use of basic substance are provided in the review report.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/82

of 27 January 2021

authorising the placing on the market of 6'-sialyllactose sodium salt 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 31 January 2019, the company Glycom A/S ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place 6'-sialyllactose ('6'-SL') sodium salt, obtained by microbial fermentation with a genetically modified strain of *Escherichia coli,* strain K12 DH1, on the Union market as a novel food. The applicant requested for 6'-SL sodium salt to be used as a novel food in unflavoured pasteurised and unflavoured sterilised milk products, flavoured and unflavoured fermented milk based products including heat-treated products, beverages (flavoured drinks excluding drinks with a pH less than 5), cereal bars, infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]), milk-based drinks and similar products intended for young children, total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([4]) intended for the general population, excluding infants and young children. The applicant also proposed that food supplements containing 6'-SL sodium salt should not be used if other foods with added 6'-SL sodium salt are consumed on the same day.

(4) On 31 January 2019, the applicant also made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application, namely, the proprietary analytical reports on the structure comparison via nuclear magnetic resonance ('NMR') of 6'-SL produced by bacterial fermentation with 6'-SL naturally present in human milk ([5]); the detailed characterisation data on the production bacterial strains ([6])

([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]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).
([5]) Glykos Finland LTD 2018 (unpublished).
([6]) Glycom 2019 (unpublished).

and their certificates ([7]); the specifications for the raw materials and processing aids ([8]); the certificates of analyses of the various 6'-SL sodium salt batches ([9]); the analytical methods and validation reports ([10]); the 6'-SL sodium salt stability reports ([11]); the detailed description of the production process ([12]); the laboratory accreditation certificates ([13]); the 6'-SL intake assessment reports ([14]); an *in vitro* mammalian cell micronucleus test with 6'-SL sodium salt ([15]); an *in vitro* mammalian cell micronucleus test with the related compound 3'-sialyllactose ('3'-SL') sodium salt ([16]); a bacterial reverse mutation test with 6'-SL sodium salt ([17]); a bacterial reverse mutation test with 3'-SL sodium salt ([18]); a 14-day oral toxicity study in the neonatal rat with 6'-SL sodium salt ([19]); a 90-day oral toxicity study in the neonatal rat with 6'-SL sodium salt, including the summary table of the statistically significant observations ([20]); a 14-day oral toxicity study in the neonatal rat with 3'-SL sodium salt ([21]); and a 90-day oral toxicity study in the neonatal rat with 3'-SL sodium salt, including the summary table of the statistically significant observations ([22]).

(5) On 16 May 2019, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of 6'-SL sodium salt as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(6) On 23 March 2020, the Authority adopted its scientific opinion 'Safety of 6'-sialyllactose (6'-SL) sodium salt as a novel food pursuant to Regulation (EC) No 2015/2283' ([23]).

(7) In its scientific opinion, the Authority concluded that 6'-SL sodium salt is safe under the proposed conditions of use for the proposed target populations. Therefore, that scientific opinion gives sufficient grounds to establish that 6'-SL sodium salt, when used in unflavoured pasteurised and unflavoured sterilised milk products, flavoured and unflavoured fermented milk based products including heat-treated products, beverages (flavoured drinks excluding drinks with a pH less than 5), cereal bars, infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013, milk-based drinks and similar products intended for young children, total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013, foods for special medical purposes as defined in Regulation (EU) No 609/2013, and in food supplements as defined in Directive 2002/46/EC, complies with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority considered that it could not have reached its conclusions on the safety of the 6'-SL sodium salt without the data from the proprietary analytical reports on the structure comparison via NMR of 6'-SL produced by bacterial fermentation with 6'-SL naturally present in human milk; the detailed characterisation data on the production bacterial strains and their certificates; the specifications for the raw materials and processing aids; the certificates of analyses of the various 6'-SL sodium salt batches; the analytical methods and validation reports; the 6'-SL sodium salt stability reports; the detailed description of the production process; the laboratory accreditation certificates, the 6'-SL intake assessment reports; the *in vitro* mammalian cell micronucleus test with 6'-SL sodium salt; the bacterial reverse mutation test with 6'-SL sodium salt; the 14-day oral toxicity study in the neonatal rat with 6'-SL sodium salt; and the 90-day oral toxicity study in the neonatal rat with 6'-SL sodium salt, including the summary table of the statistically significant observations.

([7]) Glycom/DSMZ 2018 (unpublished).
([8]) Glycom 2019 (unpublished).
([9]) Glycom 2019 (unpublished).
([10]) Glycom 2019 (unpublished).
([11]) Glycom 2019 (unpublished).
([12]) Glycom 2018 (unpublished).
([13]) Glycom 2019 (unpublished).
([14]) Glycom 2019 (unpublished).
([15]) Gilby 2018 (unpublished).
([16]) Gilby 2019 (unpublished).
([17]) Šoltésová, 2018a (unpublished).
([18]) Šoltésová, 2018b (unpublished).
([19]) Flaxmer 2018a (unpublished).
([20]) Flaxmer 2018b (unpublished).
([21]) Stannard 2019a (unpublished).
([22]) Stannard 2019b (unpublished).
([23]) EFSA Journal 2020;18(5):6097.

(9) Following the receipt of the Authority's scientific opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the analytical reports on the structure comparison via nuclear magnetic resonance NMR of 6'-SL produced by bacterial fermentation with 6'-SL naturally present in human milk; the detailed characterisation data on the production bacterial strains and their certificates; the specifications for the raw materials and processing aids; the certificates of analyses of the various 6'-SL sodium salt batches; the analytical methods and validation reports; the 6'-SL sodium salt stability reports; the detailed description of the production process; the laboratory accreditation certificates; the 6'-SL intake assessment reports; the *in vitro* mammalian cell micronucleus test with 6'-SL sodium salt; the bacterial reverse mutation test with 6'-SL sodium salt; the 14-day oral toxicity study in the neonatal rat with 6'-SL sodium salt; and the 90-day oral toxicity study in the neonatal rat with 6'-SL sodium salt, including the summary table of the statistically significant observations, and to clarify their claim to an exclusive right of reference to these studies, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.

(10) The applicant declared that, at the time the application was made, they held proprietary and exclusive rights of reference to the studies under national law and that therefore third parties could not lawfully access or use those studies.

(11) 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 data contained in the applicant's file which served as a basis for the Authority to establish the safety of the novel food and to reach its conclusions on the safety of 6'-SL sodium salt, and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of any subsequent applicant for a period of 5 years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of 6'-SL sodium salt should be restricted to the applicant for that period.

(12) However, restricting the authorisation of 6'-SL sodium salt and of the reference to the data contained in the applicant's file to the sole use by 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.

(13) In line with the conditions of use of food supplements containing 6'-SL sodium salt as proposed by the applicant and assessed by the Authority, it is necessary to inform consumers with an appropriate label that food supplements containing 6'-SL sodium salt should not be consumed the same day, if other foods with added 6'-SL sodium salt are consumed the same day.

(14) The Annex to Regulation (EU) 2017/2470 should be therefore be 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. 6'-sialyllactose ('6'-SL') sodium salt 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 5 years from the date of entry into force of this Regulation only the initial applicant:

Company: Glycom A/S;

Address: Kogle Allé 4, DK-2970 Hørsholm, Denmark,

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 or with the agreement of the applicant.

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.

Article 2

The data contained in the application file on the basis of which 6'-sialyllactose sodium salt has been assessed by the Authority, claimed by the applicant as fulfilling the requirements laid down in Article 26(2) of Regulation 2015/2283, shall not be used for the benefit of any subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of the applicant.

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, 27 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

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

'Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requi-reme-nts	Data Protection
6'-Sialyllactose (6'-SL) sodium salt (microbial source)	***Specified food category***	***Maximum levels (expressed as 6'-Sialyllactose)***	The designation of the novel food on the labelling of the foodstuffs containing it shall be "6'-Sialyllactose sodium salt". The labelling of food supplements containing 6'-Sialyllactose (6'-SL) sodium salt shall bear a statement that they should not be consumed: a) if foods containing added 6'-Sialyllactose sodium salt are consumed on the same day. b) by infants and young children		Authorised on 17 February 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Allé 4, DK-2970 Hørsholm, Denmark. During the period of data protection, the novel food 6'-sialyllactose sodium salt is authorised for placing on the market within the Union only by Glycom A/S, unless a subsequent applicant obtains authorisation for the 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 Glycom A/S.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0,5 g/L			
	Unflavoured fermented milk-based products	0,5 g/L (beverages)			
		2,5 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	0,5 g/L (beverages)			
		5,0 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0,5 g/L			
	Cereal bars	5,0 g/kg			
	Infant formula as defined under Regulation (EU) No 609/2013	0,4 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined under Regulation (EU) No 609/2013	0,3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Processed cereal-based food and baby food for infants and young children as defined under Regulation (EU) No 609/2013	0,3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
		2,5 g/kg for products other than beverages			

	Milk based drinks and similar products intended for young children	0,3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			End date of the data protection: 17 February 2026.'
	Total diet replacement foods for weight control as defined under Regulation (EU) No 609/2013	1,0 g/L (beverages)			
		10,0 g/kg (products other than beverages)			
	Food for special medical purposes as defined under Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended			
	Food Supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	1,0 g/day			

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

'Authorised Novel Food	Specification
6'-Sialyllactose ("6'-SL") sodium salt (microbial source)	**Description:** 6'-Sialyllactose (6'-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 6'-sialyl-lactulose, and sialic acid. **Source:** Genetically modified strain of *Escherichia coli* K-12 DH1 **Definition:** Chemical formula: $C_{23}H_{38}NO_{19}Na$ Chemical name: N-Acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Molecular mass: 655,53 Da CAS No 157574-76-0 **Characteristics/Composition:** Appearance: White to off-white powder or agglomerate Sum of 6'-Sialyllactose sodium salt, D-Lactose and Sialic acid (% of dry matter): ≥ 94,0 % (w/w) 6'-Sialyllactose sodium salt (% of dry matter): ≥ 90,0 % (w/w) D-Lactose: ≤ 5,0 % (w/w) Sialic acid: ≤ 2,0 % (w/w) 6'-Sialyl-lactulose: ≤ 3,0 % (w/w) Sum of other carbohydrates: ≤ 3,0 % (w/w) Moisture: ≤ 6,0 % (w/w) Sodium: 2,5-4,5 % (w/w) Chloride: ≤ 1,0 % (w/w) pH (20 °C, 5 % solution): 4,5-6,0 Residual protein: ≤ 0,01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1 000 CFU/g *Enterobacteriaceae*: ≤ 10 CFU/g *Salmonella* sp.: Absence in 25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg

CFU: Colony Forming Units; EU: Endotoxin Units.'

COMMISSION IMPLEMENTING REGULATION (EU) 2021/83

of 27 January 2021

amending Implementing Regulation (EU) 2020/466 as regards the performance of official controls and other official activities by specifically authorised natural persons and the period of application of temporary measures

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([1]), and in particular Article 141(1) thereof,

Whereas:

(1) Regulation (EU) 2017/625 lays down rules for, inter alia, the performance of official controls and of other official activities by the competent authorities of Member States. It also empowers the Commission to adopt, by means of an implementing act, appropriate temporary measures necessary to contain risks to human, animal and plant health and animal welfare, if it has evidence of a serious disruption in a Member State's control system.

(2) In order to address the specific circumstances due to the ongoing crisis related to coronavirus disease (COVID-19), Commission Implementing Regulation (EU) 2020/466 ([2]) allows Member States to apply temporary measures in relation to official controls and other official activities.

(3) Member States have informed the Commission that, in view of the crisis linked to COVID-19, certain serious disruptions in the functioning of their control systems, difficulties to perform official controls and other official activities on official certificates and official attestations with respect to movements of animals and goods into the Union and within the Union and difficulties to organise physical meetings with operators and their staff in the context of official controls will persist beyond 1 February 2021.

(4) Member States have also informed the Commission of other disruptions related to the capacity to deploy suitable staff, as required by Regulation (EU) 2017/625, in the context of official controls and other official activities.

(5) In order to address these serious disruptions, which are likely to persist in the coming months, and to facilitate the planning and the performance of official controls and other official activities during the crisis linked to COVID-19, the possibility to entrust specifically authorised natural persons with official controls and other official activities, as previously laid down in Implementing Regulation (EU) 2020/466 until 1 August 2020, should be reintroduced and the period of application of Implementing Regulation (EU) 2020/466 should be prolonged until 1 July 2021.

(6) Implementing Regulation (EU) 2020/466 should therefore be amended accordingly.

([1]) OJ L 95, 7.4.2017, p. 1.

([2]) Commission Implementing Regulation (EU) 2020/466 of 30 March 2020 on temporary measures to contain risks to human, animal and plant health and animal welfare during certain serious disruptions of Member States' control systems due to coronavirus disease (COVID-19) (OJ L 98, 31.3.2020, p. 30).

(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

Implementing Regulation (EU) 2020/466 is amended as follows:

(1) the following Article 3 is inserted:

'*Article 3*

Official controls and other official activities may exceptionally be performed by one or more natural persons specifically authorised by the competent authority on the basis of their qualifications, training and practical experience, who are in contact with the competent authority by any available means of communication, and who are required to follow the instructions of the competent authority for the performance of such official controls and other official activities. Such persons shall act impartially, and they shall be free from any conflict of interest as regards the official controls and other official activities performed by them.';

(2) in the second paragraph of Article 6, the date '1 February 2021' is replaced by the date '1 July 2021'.

Article 2

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

It shall apply from 2 February 2021.

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

Done at Brussels, 27 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COUNCIL DECISION (EU) 2021/84

of 25 January 2021

appointing a member and an alternate member, proposed by the Republic of Estonia, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal of the Estonian Government,

Whereas:

(1) On 10 December 2019, 20 January 2020, 3 February 2020 and 26 March 2020 the Council adopted, respectively, Decisions (EU) 2019/2157 ([1]), (EU) 2020/102 ([2]), (EU) 2020/144 ([3]) and (EU) 2020/511 ([4]), appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025. On 8 June 2020, the Council adopted Decision (EU) 2020/766 ([5]) appointing the members and alternate members of the Committee of the Regions for the period from 1 February 2020 to 25 January 2025. On 30 July 2020, the Council adopted Decision (EU) 2020/1153 ([6]) appointing members and alternate members of the Committee of the Regions.

(2) A member's seat on the Committee of the Regions has become vacant following the passing away of Mr Mikk PIKKMETS.

(3) An alternate member's seat will become vacant following the appointment of Mr Andres JAADLA as a member of the Committee of the Regions,

HAS ADOPTED THIS DECISION:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025:

(a) as member:

— Mr Andres JAADLA, Representative of a local body with political accountability to an elected Assembly: *Rakvere City Council;*

and

([1]) Council Decision (EU) 2019/2157 of 10 December 2019 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 327, 17.12.2019, p. 78).
([2]) Council Decision (EU) 2020/102 of 20 January 2020 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 20, 24.1.2020, p. 2).
([3]) Council Decision (EU) 2020/144 of 3 February 2020 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 32, 4.2.2020, p. 16).
([4]) Council Decision (EU) 2020/511 of 26 March 2020 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 113, 8.4.2020, p. 18).
([5]) Council Decision (EU) 2020/766 of 8 June 2020 appointing the members and alternate members of the Committee of the Regions for the period from 1 February 2020 to 25 January 2025 (OJ L 187, 12.6.2020, p. 3).
([6]) Council Decision (EU) 2020/1153 of 30 July 2020 appointing members and alternate members of the Committee of the Regions (OJ L 256, 5.8.2020, p. 12).

(b) as alternate member:

— Ms Varje TIPP, Representative of a local body with political accountability to an elected Assembly: *Pärnu City Council*.

Article 2

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

Done at Brussels, 25 January 2021.

For the Council
The President
J. BORRELL FONTELLES

COMMISSION IMPLEMENTING DECISION (EU) 2021/85

of 27 January 2021

on the equivalence to the requirements of Regulation (EU) No 648/2012 of the European Parliament and of the Council of the regulatory framework of the United States of America for central counterparties that are authorised and supervised by the U.S. Securities and Exchange Commission

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories ([1]), and in particular Article 25(6) thereof,

Whereas:

(1) The procedure for recognition of central counterparties ('CCPs') established in third countries set out in Article 25 of Regulation (EU) No 648/2012 aims to allow CCPs established and authorised in third countries whose regulatory standards are equivalent to those laid down in that Regulation to provide clearing services to clearing members or trading venues established in the Union. That recognition procedure and the equivalence decisions provided for therein thus contribute to the achievement of the overarching aim of Regulation (EU) No 648/2012 to reduce systemic risk by extending the use of safe and sound CCPs to clear over-the-counter ('OTC') derivative contracts, including where those CCPs are established and authorised in a third country.

(2) In order for a third-country legal regime to be considered equivalent to the legal regime of the Union in respect of CCPs, the substantive outcome of the applicable legal and supervisory arrangements should be equivalent to Union requirements in respect of the regulatory objectives they achieve. The purpose of such equivalence assessment is therefore to verify whether the legal and supervisory arrangements of the third country concerned ensure that CCPs established and authorised therein do not expose clearing members and trading venues established in the Union to a higher level of risk than the latter could be exposed to by CCPs authorised in the Union and, consequently, do not pose unacceptable levels of systemic risk in the Union.

(3) The assessment whether the legal and supervisory arrangements of the United States of America (USA) are equivalent to those of the Union should therefore not only be based on a comparative analysis of the legally binding requirements applicable to CCPs in the USA, but also on an assessment of the outcome of those requirements, and their adequacy to mitigate the risks that clearing members and trading venues established in the Union may be exposed to.

(4) In accordance with Article 25(6) of Regulation (EU) No 648/2012, three conditions need to be fulfilled to determine that the legal and supervisory arrangements of a third country regarding CCPs authorised therein are equivalent to those laid down in that Regulation.

(5) According to the first condition, CCPs authorised in a third country must comply with legally binding requirements which are equivalent to the requirements laid down in Title IV of Regulation (EU) No 648/2012.

([1]) OJ L 201, 27.7.2012, p. 1.

(6) The U.S. Securities and Exchange Commission (the 'SEC') is the competent authority for the authorisation and supervision of CCPs in relation to transactions in securities and derivative contracts that are based on a single security, loan or a narrow-based group or index of securities ('security-based derivatives'). The derivative contracts falling under the competence of the SEC therefore correspond to a subset of the derivative contracts covered by the provisions on CCPs set out in Regulation (EU) No 648/2012. Other derivatives contracts fall under the competence of the U.S. Commodity Futures Trading Commission (the 'CFTC'), in relation to which the Commission has already adopted Commission Implementing Decision (EU) 2016/377 ([2]). The current assessment thus relates to the equivalence of the legal and supervisory arrangements applicable in the USA to CCPs supervised by the SEC, and not to the legal and supervisory arrangements for CCPs which provide clearing services falling under the competence of the CFTC. Where a CCP is supervised by both the SEC and the CFTC, this Decision should therefore only concern that CCP in so far as it provides clearing services falling under the competence of the SEC.

(7) The legally binding requirements applicable in the USA to CCPs supervised by the SEC are set out in the rules applicable to 'clearing agencies' contained in the Securities Exchange Act of 1934 ([3]) ('the Exchange Act'), the Dodd-Frank Wall Street Reform and Consumer Protection Act ([4]) ('the Dodd-Frank Act') and the regulations adopted by the SEC thereunder. Moreover, the rules, policies and procedures of CCPs that have been registered by the SEC are legally binding upon the CCP. On 1 October 2020, the SEC issued a Staff Report describing the applicable rules and how they apply to CCPs supervised by the SEC ([5]).

(8) 'CCPs' are defined by the SEC as clearing agencies that interpose themselves between counterparties, acting as the buyer to every seller and the seller to every buyer. The term 'clearing agency' is defined in Section 23(A) of the Securities Exchange Act of 1934 as any person who acts as an intermediary in making payments or deliveries or both in connection with transactions in securities or who provides facilities for the comparison of data regarding the terms of settlement of securities transactions, to reduce the number of settlements of securities transactions, or for the allocation of securities settlement responsibilities.

(9) The SEC may designate clearing agencies as clearing agencies with a more complex risk profile. A CCP clearing security-based swaps is always considered to have a more complex risk profile. Moreover, the Financial Stability Oversight Council may designate a CCP as systemically important pursuant to the Dodd-Frank Act. Such CCPs with a more complex risk profile or that are systemically important are considered to be 'covered clearing agencies'. The enhanced framework laid down in SEC Rule 17Ad-22(d) and (e) apply to such CCPs. This Decision only concerns the equivalence of the US legally binding requirements applicable to CCPs which have to comply with those enhanced rules.

(10) According to the Exchange Act, the Dodd-Frank Act and the SEC's regulations, a CCP clearing securities or security-based derivatives, referred to in that act as security-based swaps, is required to register with the SEC or to seek exemption from registration.

(11) The Exchange Act does not prescribe specific tools or arrangements on how to achieve the requirements laid down in it. While a CCP may consider its unique characteristics and circumstances when laying down its rules and procedures, such as its ownership and governance structures, effects on direct and indirect participants, its membership base, the markets served and the risks inherent in products cleared, its internal rules and procedures must provide prescriptive detail on the way in which it will meet the requirements laid down in the Exchange Act. Once registered by the SEC, the rules, policies and procedures approved by the SEC become legally binding on the CCP.

([2]) Commission Implementing Decision (EU) 2016/377 of 15 March 2016 on the equivalence of the regulatory framework of the United States of America for central counterparties that are authorised and supervised by the Commodity Futures Trading Commission to the requirements of Regulation (EU) No 648/2012 of the European Parliament and of the Council (OJ L 70, 16.3.2016, p. 32).

([3]) Section 3(a)(23) and 17A.

([4]) Titles VII and VIII.

([5]) Staff Report on the Regulation of Clearing Agencies by Division of Trading and Markets Office of Compliance Inspections and Examinations, https://www.sec.gov/files/regulation-clearing-agencies-100120.pdf

(12) Upon registration by the SEC, the CCP becomes a 'self-regulatory organization' under Section 3(a)26 of the Exchange Act and must, as such, file any rule change with the SEC for approval. The SEC will verify that the proposed rule change is consistent with the standards laid down in the Exchange Act and in the SEC's regulations.

(13) The legally binding requirements in the USA with respect to CCPs qualified as covered clearing agencies comprise a two-tiered structure. The first tier consists of the primary rules and requirements laid down in Section 3a(23) and 17A of the Exchange Act, Titles VII and VIII of the Dodd-Frank Act, and in the SEC's regulations, in particular Rule 17Ad-22 ('primary rules'). The second tier consists of the internal rules and procedures of such CCPs, which are legally binding on the CCPs upon their registration by the SEC and, therefore, form part of the rules the compliance with which is supervised by the SEC. When assessing whether CCPs qualified as covered clearing agencies comply with legally binding requirements which are equivalent to the requirements laid down in Title IV of Regulation (EU) No 648/2012, the Commission has to consider the legally binding requirements laid down in the internal rules and procedures of those CCPs alongside the requirements laid down in the Exchange Act and the Dodd-Frank Act and the SEC's regulations.

(14) To be registered by the SEC, a CCP qualified as a covered clearing agency, and its internal rules, must meet the high-level standards set out in the primary rules. Those requirements, complemented by the internal rules and procedures of the CCP, deliver substantive outcomes equivalent to the effects of the rules laid down in Title IV of Regulation (EU) No 648/2012. In particular, a CCP qualified as a covered clearing agency must fulfil requirements with respect to its organisational structure and rules to ensure the prompt and accurate clearing and settlement, as well as the safeguard of securities and funds under its control, and to ensure the protection of investors and the public interest, including requirements such as those relating to senior management, risk management and internal control mechanisms, record-keeping, qualifying holdings, information transmitted to the competent authority, conflicts of interest, business continuity, outsourcing, conduct of business and segregation, as well as liquidity risk, collateral, investment policy, and settlement risk. Other requirements relate to the conditions for participation and fees, and rules for disciplining violations of the CCP's rules by participants.

(15) Nevertheless, the legally binding requirements applicable to CCPs qualified as covered clearing agencies differ in some aspects from to the rules in Title IV of Regulation (EU) No 648/2012.

(16) Firstly, the primary rules with respect to liquidity risks do not require CCPs qualified as covered clearing agencies to maintain eligible liquidity resources to meet the 'cover 2 principle' laid down in Article 44 of Regulation (EU) No 648/2012, that is, liquid resources to at least cover the default of the two clearing members to which it has the largest exposures. In the USA, CCPs qualified as covered clearing agencies are nevertheless required to set up procedures to cover any uncovered liquidity shortfall, ensuring that committed resources are available where losses exceed the default of the clearing member to which it has the largest exposure. Additionally, the primary rules require CCPs qualified as covered clearing agencies to apply the 'cover 2 principle' where they clear security-based derivatives. Although this is a different approach to the 'cover 2 principle' laid down in 42, 43 and 44 of Regulation (EU) No 648/2012, the primary rules together with the CCPs' internal rules and procedures deliver substantive outcomes equivalent to the effects of the 'cover 2 principle' laid down in Union rules.

(17) Secondly, the primary rules do not provide for a minimum liquidation period. However, all CCPs qualified as covered clearing agencies apply minimum liquidation periods of 2 to 5 days in accordance with their internal rules and procedures. Union rules set out minimum liquidation periods of 2 days for non-OTC derivative contracts and 5 days for OTC derivative contracts, typically with margin collected on a net basis. Therefore, the CCPs' internal rules and procedures deliver substantive outcomes equivalent to the effects of the Union rules on liquidation periods.

(18) Thirdly, Union law requires the application of at least one of three anti-procyclicality measures to ensure that initial margins do not fall too low in stable economic times and do not increase precipitously in times of stress. In doing so, such measures deliver stable and conservative margins. The primary rules contain no such specific requirement. CCPs qualified as covered clearing agencies, however, do have in place internal rules and procedures with anti-procyclical effects. Therefore, the CCPs' internal rules and procedures deliver substantive outcomes equivalent to the effects of the Union rules on anti-procyclicality.

(19) Lastly, with regard to segregation and portability of positions and collateral of clients of clearing members, Rule 17Ad-22(e)(14) requires that the rules, policies and procedures of CCPs qualified as covered clearing agencies enable the segregation and portability of positions of a clearing member's client and the related collateral, and to effectively protect such positions and collateral from the default or insolvency of that clearing member where those CCPs clear security-based derivatives or have a more complex risk profile and, thus, follows a similar approach to the rules contained in Title IV of Regulation (EU) No 648/2012. For cash securities and listed options, however, the primary rules rely on the rules applicable to the clearing members. In those markets, the rules applicable to clearing members already ensure the appropriate level of segregation and portability and, therefore, adequately protect client positions and collateral. Although following a different approach to segregation and portability at the level of the clearing members, and not that of the CCP, with regard to those markets, both approaches result in similar outcomes with regard to client protection.

(20) The legal and supervisory arrangements of the USA applicable to CCPs qualified as covered clearing agencies should therefore be deemed equivalent, provided that the internal rules and procedures of a CCP applying for recognition meets certain requirements with respect to risk management. In particular, a CCP should apply a 2-day liquidation period with respect to non-OTC derivative contracts and a 5-day liquidation period with respect to OTC derivative contracts, both on a net basis. Moreover, the CCP should apply measures designed to limit pro-cyclicality that are equivalent in delivering stable and conservative margins to any of the three measures set out under Regulation (EU) No 648/2012.

(21) The Commission concludes that the legal and supervisory arrangements of the SEC applying to CCPs qualified as covered clearing agencies and comprising the requirements laid down in the Exchange Act, the Dodd-Frank Act and the SEC's regulations, and in the internal rules and procedures of registered CCPs qualified as covered clearing agencies, should be considered as legally binding requirements which are equivalent to the requirements laid down in Title IV of Regulation (EU) No 648/2012, to the extent that they meet the standards set out in this Decision with respect to risk management.

(22) Only CCPs that comply with the rules applicable to covered clearing agencies and with legally binding requirements meeting the risk management standards set out in this Decision may be eligible for recognition by the European Securities and Markets Authority (ESMA). ESMA should verify, in accordance with Article 25(2)(b) of Regulation (EU) No 648/2012, that those risk management standards are part of the internal rules and procedures of any CCP that is supervised by the SEC and is applying for recognition in the Union. In particular, ESMA should check that the CCP applies a 2-day liquidation period with respect to non-OTC derivative contracts and a 5-day liquidation period with respect to OTC derivative contracts, both on a net basis, and that the CCP applies measures designed to limit procyclicality that are equivalent in delivering stable and conservative margins to any of the three measures set out under Regulation (EU) No 648/2012.

(23) According to Article 25(6), point (b), of Regulation (EU) No 648/2012, the legal and supervisory arrangements in respect of CCPs established in a third country must also provide for effective supervision and enforcement of CCPs in that jurisdiction on an ongoing basis.

(24) The SEC conducts ongoing monitoring of CCPs' under its supervision. In addition to its power to review and approve rule changes filed by a registered CCP, the SEC has wide powers to request copies of CCPs' books and records and to examine and conduct on-site inspections to assess existing and emerging risks, to monitor compliance by the CCP with rules applicable to it, as well as the CCP's oversight of compliance by its participants with its internal rules and procedures. The SEC has the power to ask for changes in rules and procedures and may institute civil actions seeking injunctive and other remedies, or administrative proceedings in case of infringement of the applicable rules. The SEC's examination may result in the revocation of the registration where deficiencies are not addressed. Those powers apply also to CCPs qualified as covered clearing agencies.

(25) The Commission therefore concludes that the legal and supervisory arrangements in respect of CCPs, including those that are qualified as covered clearing agencies, provide for effective supervision and enforcement on an ongoing basis.

(26) According to Article 25(6), point (c), of Regulation (EU) No 648/2012, the legal and supervisory arrangements of a third country must include an effective equivalent system for the recognition of CCPs authorised under third-country legal regimes ('third-country CCPs').

(27) Non-US CCPs may apply to the SEC for registration as a 'clearing agency'. So far, the SEC has required such registration, or an exemption from registration, for clearing services in relation to US securities provided to US persons or in relation to security-based swaps.

(28) Non-US CCPs registered with the SEC must comply with the relevant requirements of the USA, including SEC regulations applicable to registered clearing agencies qualified as covered clearing agencies. The Exchange Act, however, grants the SEC broad exemptive authority. Under Section 17A(b)(1) of the Exchange Act, the SEC may provide exemptive relief from regulatory requirements if it is consistent with the public interest, the protection of investors, and the purposes of Section 17A of the Exchange Act, including the prompt and accurate clearance and settlement of securities transactions and the safeguarding of securities and funds. Under Section 36 of that Act, the SEC may, conditionally or unconditionally, exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from provisions of the Exchange Act or rules or regulations thereunder, to the extent that such exemption is necessary or appropriate in the public interest and is consistent with the protection of investors. In addition, under Section 17A(k) of the Exchange Act, the SEC may grant an exemption, conditionally or unconditionally, from clearing agency registration for the clearing of security-based swaps if the SEC determines that the clearing agency is subject to comparable, comprehensive supervision and regulation by the appropriate government authorities in the home country of the clearing agency.

(29) The SEC has issued a policy statement and guidance ([6]) addressed to CCPs authorised in the Union. The policy statement provides a high-level summary of the legal framework that applies to SEC-registered CCPs and explains the process for applying for registration and exemptions. It also provides examples of how the SEC has applied its exemptive powers to avoid to impose requirements that are unnecessary, duplicative, or inconsistent relative to requirements applicable to a CCP in a home jurisdiction, where the framework of that jurisdiction is generally consistent with the Principles of Financial Market Infrastructures (PFMIs) issued by the Committee on Payments and Market Infrastructures and the International Organization of Securities Commissions. Moreover, the policy statement and guidance sets out the factors that the SEC will consider when assessing requests for exemptions and explains that the SEC will consider the extent to which a CCP is subject to appropriate supervision and enforcement by the national competent authority supervising the CCP or other relevant authorities in its home jurisdiction. On that basis, and subject to the SEC's assessment and determination that the exemption is consistent with the Exchange Act, the SEC may grant a CCP established outside the USA an exemption to avoid the application of an SEC requirement that is unnecessary, duplicative, or inconsistent relative to the requirements laid down in rules and regulations applicable to the CCP in its home jurisdiction in a way comparable to the equivalent system for the recognition of third-country CCPs laid down in Regulation (EU) No 648/2012.

(30) The Commission therefore concludes that the legal and supervisory arrangements of the SEC provide for an effective equivalent system for the recognition of third-country CCPs.

([6]) Statement on Central Counterparties Authorized under the European Markets Infrastructure Regulation Seeking to Register as a Clearing Agency or to Request Exemptions from Certain Requirements Under the Securities Exchange Act of 1934, [Release No. 34-90492], issued on 30 November 2020.

(31) The conditions laid down in Article 25(6) of Regulation (EU) No 648/2012 are therefore considered to be met by the legal and supervisory arrangements applicable in the USA to CCPs which must comply with the rules applicable to covered clearing agencies and which are registered and supervised by the SEC, and those legal and supervisory arrangements should be considered equivalent to the requirements laid down in Regulation (EU) No 648/2012.

(32) This Decision is based on the legally binding requirements in the USA relating to CCPs which must comply with the rules applicable to covered clearing agencies at the time of the adoption of this Decision. The Commission, in cooperation with ESMA, should monitor on a regular basis the evolution of the legal and supervisory framework applicable in the USA to such CCPs and the fulfilment of the conditions on the basis of which this Decision has been taken.

(33) At least every 3 years, the Commission should undertake a review of the grounds on the basis of which this Decision was adopted, including the legal and supervisory arrangements applicable in the USA to CCPs which must comply with the rules applicable to covered clearing agencies and which are registered and supervised by the SEC. Such regular reviews are without prejudice to the Commission's power to undertake a specific review at any time where relevant developments make it necessary for the Commission to re-assess the determination made by this Decision. Based on the findings arising from a regular or specific review, the Commission may decide to amend or repeal this Decision at any time, in particular where developments affect the conditions on the basis of which this Decision is adopted.

(34) The measures provided for in this Decision are in accordance with the opinion of the European Securities Committee,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of Article 25 of Regulation (EU) No 648/2012, the legal and supervisory arrangements of the United States of America for central counterparties (CCPs) which must comply with the rules applicable to covered clearing agencies laid down in Sections 3(a)(23) and 17A of the Securities Exchange Act of 1934, in Titles VII and VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act and in regulations adopted by the U.S. Securities and Exchange Commission thereunder, shall be considered equivalent to the requirements laid down in Regulation (EU) No 648/2012 where the internal rules and procedures of such a CCP include specific risk management measures ensuring that initial margins are calculated and collected on the basis of the following parameters:

(a) in the case of derivative contracts executed on regulated markets, a liquidation period of 2 days calculated on a net basis;

(b) in the case of OTC derivative contracts, a liquidation period of 5 days calculated on a net basis;

(c) in the case of all derivative contracts, measures designed to limit procyclicality equivalent to at least one of the following:

  (i) measures applying a margin buffer at least equal to 25 % of the calculated margins which the central counterparty allows to be temporarily exhausted in periods where calculated margin requirements are rising significantly;

  (ii) measures assigning at least 25 % weight to stressed observations in the look-back period;

  (iii) measures ensuring that margin requirements are not lower than those that would be calculated using volatility estimated over a 10 year historical look-back period.

Article 2

No later than 3 years after the date of entry into force of this Decision and then no later than every 3 years after each previous review under this Article, the Commission shall undertake a review of the grounds on which the determination under Article 1 was made.

Article 3

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

Done at Brussels, 27 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

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