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⁽¹⁾ Text with EEA relevance.

EN

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

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II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2018/1554**of 15 October 2018****amending Regulation (EU) No 1370/2013 as regards the quantitative limitation for buying-in skimmed milk powder**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Article 3 of Council Regulation (EU) No 1370/2013 ⁽¹⁾ sets a quantitative limitation for buying-in skimmed milk powder at the fixed price referred to in Article 2 of that Regulation. Once this limit is reached, buying-in is to be carried out by way of a tendering procedure to determine the maximum buying-in price.
- (2) Council Regulation (EU) 2018/147 ⁽²⁾ amended Regulation (EU) No 1370/2013 by setting the quantitative limitation for buying-in skimmed milk powder at a fixed price to zero for the year 2018. This was done to avoid skimmed milk powder being bought-in at a fixed price in a situation where this would not be in keeping with the objectives of the safety net.
- (3) Within the milk and milk product sector, fat and protein prices continue to diverge. In 2018, Union market prices for skimmed milk powder have remained below the public intervention level, while butter prices are more than double the public intervention level.
- (4) Raw milk prices paid to farmers in 2018 are at a level that renders dairy farming remunerative because of the current strong demand for butter and cheese despite the relatively low prices for dairy protein. The operation of public intervention in 2018 under a tendering procedure has not prevented raw milk prices to maintain these levels.
- (5) The fundamentals for the milk and milk product market in terms of supply, demand and price evolution are not expected to change substantially in 2019, in particular as regards the divergence between dairy fat and protein prices. It is therefore appropriate to set the quantitative limitation for buying-in skimmed milk powder at a fixed price to zero for the year 2019.
- (6) Regulation (EU) No 1370/2013 should therefore be amended accordingly.
- (7) In order to ensure that the temporary measure provided for in this Regulation has an immediate impact on the market and to allow market operators to be informed in due time before the start of the next intervention campaign, this Regulation should enter into force on the day following that of its publication,

⁽¹⁾ Council Regulation (EU) No 1370/2013 of 16 December 2013 determining measures on fixing certain aids and refunds related to the common organisation of the markets in agricultural products (OJ L 346, 20.12.2013, p. 12).

⁽²⁾ Council Regulation (EU) 2018/147 of 29 January 2018 amending Regulation (EU) No 1370/2013 as regards the quantitative limitation for buying-in skimmed milk powder (OJ L 26, 31.1.2018, p. 6).

HAS ADOPTED THIS REGULATION:

Article 1

In Article 3(1) of Regulation (EU) No 1370/2013, the following subparagraph is added:

‘By way of derogation from the first subparagraph, the quantitative limitation for buying-in skimmed milk powder at a fixed price shall be 0 tonnes for the year 2019.’.

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 Luxembourg, 15 October 2018.

For the Council

The President

E. KÖSTINGER

COMMISSION REGULATION (EU) 2018/1555**of 17 October 2018****refusing to authorise certain health claims made on foods and referring to the reduction of disease risk****(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 17(3) 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'.
- (3) Following receipt of an application, the Authority is to inform without delay the other Member States and the Commission thereof, and 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 Laboratoire Nurilia, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Condensyl® and decreases sperm DNA damage. High sperm DNA damage is a risk factor for male subfertility/infertility (Question No EFSA-Q-2016-00665) ⁽²⁾. The claim proposed by the applicant was worded as follows: 'The combination of opuntia fruit dry extract standardised in quercetin and betalain, N-acetyl cysteine, zinc, vitamin B3, E, B6, B2, B9 and B12 in Condensyl® decreases sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index). High sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index) is a risk factor for male subfertility/infertility'.
- (6) On 5 May 2017, the Commission and the Member States received the scientific opinion 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 Condensyl® and the reduction of sperm DNA damage in the context of reducing the risk of male infertility. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (7) Following an application from Cargill R&D Centre Europe, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to sugar-free hard confectionery with at least 90 % erythritol and reduction of dental plaque which reduces the risk of caries (Question No EFSA-Q-2017-00002) ⁽³⁾. The claim proposed by the applicant was worded as follows: 'Sugar-free hard confectionery sweetened with at least 90 % Zerose® erythritol has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries'.
- (8) On 21 July 2017, the Commission and the Member States received the scientific opinion 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 sugar-free hard confectionery with at least 90 % erythritol and reduction of dental plaque which reduces the risk of dental caries. 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 2017;15(5):4775.

⁽³⁾ EFSA Journal 2017;15(7):4923.

- (9) Following an application from Biosearch Life, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to *Lactobacillus fermentum* CECT 5716 and decreases the *Staphylococcus* load in breast milk. High *Staphylococcus* load in breast milk is a risk factor for infectious mastitis (Question No EFSA-Q-2016-00318) ⁽¹⁾. The claim proposed by the applicant was worded as follows: '*Lactobacillus fermentum* CECT 5716 decreases the *Staphylococcus* load in breast milk. High *Staphylococcus* load in breast milk is a risk factor for mammary bacterial dysbiosis/mastitis'.
- (10) On 24 July 2017, the Commission and the Member States received the scientific opinion 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 *Lactobacillus fermentum* CECT 5716 and a reduction of the *Staphylococcus* load in breast milk which reduces the risk of infectious mastitis. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (11) 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 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 14(1) 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, 17 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ EFSA Journal 2017;15(7):4917.

ANNEX

Rejected health claims

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk.	Condensyl®	The combination of opuntia fruit dry extract standardised in quercetin and betalain, N-acetyl cysteine, zinc, vitamin B3, E, B6, B2, B9 and B12 in Condensyl® decreases sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index). High sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index) is a risk factor for male sub-fertility/infertility.	Q-2016-00665
Article 14(1)(a) health claim referring to a reduction of a disease risk.	Sugar-free hard confectionery with at least 90 % erythritol	Sugar-free hard confectionery sweetened with at least 90 % Zeros® erythritol has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries.	Q-2017-00002
Article 14(1)(a) health claim referring to a reduction of a disease risk.	<i>Lactobacillus fermentum</i> CECT 5716	<i>Lactobacillus fermentum</i> CECT 5716 decreases the <i>Staphylococcus</i> load in breast milk. High <i>Staphylococcus</i> load in breast milk is a risk factor for mammary bacterial dys-biosis/mastitis.	Q-2016-00318

COMMISSION REGULATION (EU) 2018/1556**of 17 October 2018****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 Laboratoires Nutrition et Cardiométabolisme, 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 Stablor®, a drink preparation with defined macro- and micronutrient composition and specific proportion of amino acids (tryptophan to neutral amino acids ratio) and decrease in visceral fat while preserving lean mass (Question No EFSA- Q-2016-00319 ⁽²⁾). The claim proposed by the applicant was worded as follows: 'In the context of a well-balanced diet and a mild caloric restriction, the addition of Stablor® contributes to decrease visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors'.
- (6) On 28 February 2017, the Commission and the Member States received the scientific opinion 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 Stablor® and reduction of visceral fat while maintaining lean body mass in the context of an energy restricted diet. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (7) Following an application from Suomen Terveystuote Oy, 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 curcumin and normal functioning of joints (Question No EFSA- Q-2016-00856 ⁽³⁾). The claim proposed by the applicant was worded as follows: 'Curcumin contributes to the normal functioning of joints'.
- (8) On 8 May 2017, the Commission and the Member States received the scientific opinion 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 curcumin and the maintenance of joint function. 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 2017;15(2):4723.

⁽³⁾ EFSA Journal 2017;15(5):4774.

- (9) Following an application from Marks and Spencer PLC, 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 carbohydrate: protein (CHO:P) ratio ≤ 1.8 on an energy basis in the context of an energy-restricted diet and body weight (Question No EFSA-Q-2016-00436 ⁽¹⁾). The claim proposed by the applicant was worded as follows: 'Helps to achieve a reduction in body weight and body fat when consumed as part of an energy restricted diet ($< 8,368$ kJ/2,000 kcal/day) for a minimum of 12 weeks'.
- (10) On 13 June 2017, the Commission and the Member States received the scientific opinion 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 a CHO:P ratio ≤ 1.8 on an energy basis consumed in the context of an energy-restricted diet and the reduction of body weight. 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 Loc Troi group, 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 Vibigaba (germinated brown rice) and reduction of body weight in the context of an energy-restricted diet (Question No EFSA- Q-2017-00032 ⁽²⁾). The claim proposed by the applicant was worded as follows: 'In the context of an energy-restricted diet contributes to weight loss'.
- (12) On 21 July 2017, the Commission and the Member States received the scientific opinion 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 Vibigaba (germinated brown rice) and the reduction of body weight in the context of an energy-restricted diet. 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 Loc Troi group, 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 Vibigaba (germinated brown rice) and maintenance of long-term normal blood glucose concentration (Question No EFSA-Q-2017-00033 ⁽³⁾). The claim proposed by the applicant was worded as follows: 'Contributes to the maintenance of normal blood glucose levels'.
- (14) On 21 July 2017, the Commission and the Member States received the scientific opinion 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 Vibigaba (germinated brown rice) and the maintenance of long-term normal blood glucose concentration. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (15) Following an application from Loc Troi group, 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 Vibigaba (germinated brown rice) and contribution to the maintenance of normal blood pressure (Question No EFSA- Q-2017-00031 ⁽⁴⁾). The claim proposed by the applicant was worded as follows: 'Contributes to the maintenance of normal blood pressure'.
- (16) On 21 July 2017, the Commission and the Member States received the scientific opinion 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 Vibigaba (germinated brown rice) and the maintenance of normal BP. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (17) Following an application from Loc Troi group, 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 Vibigaba (germinated brown rice) and contribution to the maintenance of normal blood cholesterol concentration (Question No EFSA- Q-2017-00030 ⁽⁵⁾). The claim proposed by the applicant was worded as follows: 'Contributes to the maintenance of normal blood cholesterol levels'.

⁽¹⁾ EFSA Journal 2017;15(6):4839.

⁽²⁾ EFSA Journal 2017;15(7):4915.

⁽³⁾ EFSA Journal 2017;15(7):4916.

⁽⁴⁾ EFSA Journal 2017;15(7):4914.

⁽⁵⁾ EFSA Journal 2017;15(7):4913.

- (18) On 21 July 2017, the Commission and the Member States received the scientific opinion 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 Vibigaba (germinated brown rice) and maintenance of normal blood cholesterol concentration. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (19) 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 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, 17 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Rejected health claim

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	Stablor®, a drink preparation with defined macro- and micronutrient composition and specific proportion of amino acids (tryptophan to neutral amino acids ratio)	In the context of a well-balanced diet and a mild caloric restriction, the addition of Stablor® contributes to decrease visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors.	Q-2016-00319
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Curcumin	Curcumin contributes to the normal functioning of joints.	Q-2016-00856
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	A carbohydrate:protein (CHO:P) ratio ≤ 1.8 on an energy basis in the context of an energy-restricted diet and body weight	Helps to achieve a reduction in body weight and body fat when consumed as part of an energy restricted diet ($< 8\,368\text{ kJ}/2\,000\text{ kcal/day}$) for a minimum of 12 weeks.	Q-2016-00436
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Vibigaba (germinated brown rice)	In the context of an energy-restricted diet contributes to weight loss.	Q-2017-00032
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Vibigaba (germinated brown rice)	Contributes to the maintenance of normal blood glucose levels.	Q-2017-00033
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Vibigaba (germinated brown rice)	Contributes to the maintenance of normal blood pressure.	Q-2017-00031
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Vibigaba (germinated brown rice)	Contributes to the maintenance of normal blood cholesterol levels.	Q-2017-00030

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1557**of 17 October 2018****amending Implementing Regulation (EU) 2016/1368 establishing a list of critical benchmarks used in financial markets pursuant to Regulation (EU) 2016/1011 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1011 of the European Parliament and of the Council of 8 June 2016 on indices used as benchmarks in financial instruments and financial contracts or to measure the performance of investments funds and amending Directives 2008/48/EC and 2014/17/EU and Regulation (EU) No 596/2014 ⁽¹⁾, and in particular Article 20(1), thereof,

Whereas:

- (1) Benchmarks play an important role in the determination of the price of many financial instruments and financial contracts and of the measurement of performance for many investment funds. The contribution to and administration of benchmarks are in many cases vulnerable to manipulation and persons involved often face conflict of interests.
- (2) In order to fulfil their economic role, benchmarks need to be representative of the underlying market or economic reality they reflect. Should a benchmark no longer be representative of an underlying market, such as interbank offered rates, there is a risk of negative effects on, inter alia, market integrity, the financing of households (loans and mortgages) and businesses in the Union.
- (3) Risks to users, markets and the economy of the Union generally increase where the total value of financial instruments, financial contracts and investment funds referencing a specific benchmark is high. Regulation (EU) 2016/1011 therefore establishes different categories of benchmarks and provides for additional requirements ensuring the integrity and robustness of certain benchmarks considered as being critical, including the power of competent authorities to mandate, under certain conditions, contributions to or the administration of a critical benchmark.
- (4) Commission Implementing Regulation (EU) 2016/1368 ⁽²⁾ established a list of critical benchmarks used in financial markets pursuant to Regulation (EU) 2016/1011.
- (5) Pursuant to Article 20(1) of Regulation (EU) 2016/1011, the Commission is empowered to adopt implementing acts to establish and review at least every two years a list of critical benchmarks.
- (6) In accordance with point (b) of Article 20(1) of Regulation (EU) 2016/1011, benchmarks may be included in the list of critical benchmarks where those benchmarks, inter alia, are submitted by contributors the majority of which are located in one Member State and are recognised as being critical in that Member State.
- (7) On 22 January 2018, the Swedish competent authority ('Finansinspektionen') notified the European Securities and Markets Authority ('ESMA') of its proposal to recognise the Stockholm Interbank Offered Rate ('STIBOR') as a critical benchmark, under point (b) of Article 20(1) of Regulation (EU) 2016/1011, because it is critical in Sweden and it is based on submissions of contributors, the majority of which are located in Sweden.
- (8) STIBOR is a reference rate based on an average of the interest rates at which a number of banks active on the Swedish money market are willing to lend unsecured funds to each other at different maturities. On 22 January 2018, seven banks participated in the STIBOR panel, six of which were located in Sweden and one in Denmark.

⁽¹⁾ OJ L 171, 29.6.2016, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2016/1368 of 11 August 2016 establishing a list of critical benchmarks used in financial markets pursuant to Regulation (EU) 2016/1011 of the European Parliament and of the Council (OJ L 217, 12.8.2016, p. 1).

- (9) In its assessment submitted to ESMA, Finansinspektionen concluded that the cessation of STIBOR, or its provision on the basis of input data or of a panel of contributors no longer representative of the underlying market or economic reality, could have a significant adverse impact on the functioning of financial markets in Sweden.
- (10) The assessment by Finansinspektionen illustrates that STIBOR is used as a reference in the pricing of over-the-counter ('OTC') interest rate derivatives denominated in Swedish krona ('SEK') for an outstanding notional amount of EUR 3 500 billion. Close to one fourth of SEK-denominated bonds reference STIBOR and STIBOR is used in the pricing of 75 % of total loans to Swedish households and non-financial institutions. The total value of financial instruments and financial contracts referencing STIBOR is about eight times larger than the gross national product of Sweden. STIBOR is therefore of vital importance for financial stability and market integrity in Sweden. The assessment concluded that STIBOR's discontinuity or unreliability could have a significant adverse impact on the functioning of financial markets in Sweden and on companies and consumers because it is used in loans, consumer credits products and investment funds.
- (11) On 23 February 2018, ESMA sent the Commission its opinion setting out that Swedish Finansinspektion had taken into consideration all the elements and criteria included in Article 20(3) of Regulation (EU) 2016/1011 and that it had provided quantitative data to support the case for the recognition of STIBOR as a critical benchmark, as well as analytical reasoning highlighting the crucial role of STIBOR in the Swedish economy.
- (12) Implementing Regulation (EU) 2016/1368 should therefore be amended accordingly.
- (13) In light of the crucial importance of STIBOR, its widespread use and its role in the allocation of capital in Sweden, this Regulation should enter into force as a matter of urgency.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the European Securities Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2016/1368 is replaced by the text in 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, 17 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

‘ANNEX

List of critical benchmarks pursuant to Article 20(1) of Regulation (EU) 2016/1011

No	Benchmark	Administrator	Location
1	Euro Interbank Offered Rate (EURIBOR®)	European Money Markets Institute (EMMI)	Brussels, Belgium
2	Euro Overnight Index Average (EONIA®)	European Money Markets Institute (EMMI)	Brussels, Belgium
3	London Interbank Offered Rate (LIBOR)	ICE Benchmark Administration (IBA)	London, United Kingdom
4	Stockholm Interbank Offered Rate (STIBOR)	Swedish Bankers' Association (Svenska Bankföreningen)	Stockholm, Sweden'

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1558

of 17 October 2018

concerning the authorisation of a new use of the preparation of *Lactobacillus acidophilus* (CECT 4529) as a feed additive for cats and dogs (holder of the authorisation Centro Sperimentale del Latte)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a new use of the preparation of *Lactobacillus acidophilus* (CECT 4529). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of the preparation of *Lactobacillus acidophilus* (CECT 4529) as a feed additive for cats and dogs to be classified in the additive category 'zootechnical additives'.
- (4) The preparation of *Lactobacillus acidophilus* (CECT 4529) belonging to the additive category of 'zootechnical additives', was authorised for ten years as a feed additive for laying hens by Commission Implementing Regulation (EU) 2015/38 ⁽²⁾ and for chickens for fattening by Commission Implementing Regulation (EU) 2017/2275 ⁽³⁾.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 19 April 2018 ⁽⁴⁾ that, under the proposed conditions of use, the preparation of *Lactobacillus acidophilus* (CECT 4529) does not have an adverse effect on animal health, human health and the environment. It also concluded that the additive has the potential to improve the stool consistency of cats and dogs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the preparation of *Lactobacillus acidophilus* (CECT 4529) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation 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 preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition subject to the conditions laid down in the Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) 2015/38 of 13 January 2015 concerning the authorisation of the preparation of *Lactobacillus acidophilus* CECT 4529 as a feed additive for laying hens and amending Regulation (EC) No 1520/2007 (holder of authorisation Centro Sperimentale del Latte) (OJ L 8, 14.1.2015, p. 4).

⁽³⁾ Commission Implementing Regulation (EU) 2017/2275 of 8 December 2017 concerning the authorisation of a new use of the preparation of *Lactobacillus acidophilus* (CECT 4529) as a feed additive for chickens for fattening (holder of the authorisation Centro Sperimentale del Latte) (OJ L 326, 9.12.2017, p. 47).

⁽⁴⁾ EFSA Journal 2018; 16(5):5278.

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, 17 October 2018.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU /kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1715	Centro Sperimentale del Latte	<i>Lactobacillus acidophilus</i> CECT 4529	<i>Additive composition</i> Preparation of <i>Lactobacillus acidophilus</i> CECT 4529 containing a minimum of: 5 × 10 ¹⁰ CFU/g of additive (solid form). <i>Characterisation of the active substance</i> Viable cells of <i>Lactobacillus acidophilus</i> CECT 4529. <i>Analytical method</i> ⁽¹⁾ Enumeration: spread plate method using MRS agar (EN 15787). Identification: Pulsed Field Gel Electrophoresis (PFGE).	Cats and dogs	—	5 × 10 ⁹	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eyes, skin and breathing protection.	7 November 2028

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

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1559
of 17 October 2018
concerning the authorisation of cumin tincture (*Cuminum cyminum* L.) as a feed additive 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of cumin tincture (*Cuminum cyminum* L.) as a feed additive for all animal species. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003. The applicant requested that the additive be classified in the additive category 'sensory additives'.
- (3) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 April 2018 ⁽²⁾ that, under the proposed conditions of use, cumin tincture (*Cuminum cyminum* L.) does not have adverse effects on animal health, human health or the environment. The Authority has concluded that since cumin seeds are universally recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated for feed. The Authority further noted that for the safety of the additive for users a potential to be dermal/eye irritant cannot be excluded. In addition, the additive contains a variety of compounds known to cause allergic reactions in sensitive persons. Therefore, sensitisation may occur. Consequently, appropriate protective measures should be taken.
- (4) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of this additive 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.
- (6) The applicant proposed use levels for the substances concerned to the Authority. Having regard to that proposal, the Authority considered that certain use levels are safe. For the purpose of official controls along the food chain, the recommended maximum content of the active substance should be indicated on the label of the feed additive.
- (7) The fact that the use of the substance concerned in water for drinking is not authorised should not preclude their use in compound feed, which is administered via water.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2018;16(5):5273

*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, 17 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

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
						ml of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b161	—	Cumin tincture	<i>Additive composition</i> Cumin tincture of <i>Cuminum cyminum</i> L. <i>Characterisation of the active substance</i> Tincture from <i>Cuminum cyminum</i> L. seeds as defined by the Council of Europe ⁽¹⁾. — 98 % ± 0,5 % of a water/ethanol (3:1, v/v) mixture; — 2 ± 0,5 % of plant derived compounds; — total flavonoids ≤ 300 ppm; — total polyphenols ≤ 560 ppm; — total p-menth-3-en-7-al ≤ 8 ppm; — phytochemical marker: 4-iso-propylbenzaldehyde (cuminaldehyde): 25 ± 5 ppm. Liquid form CoE No 161 <i>Method of analysis</i> ⁽²⁾ For the quantification of the phytochemical marker (4-iso-propylbenzaldehyde) in the feed additive: gas chromatography coupled with flame ionisation detection (GC-FID)	All animal species	—		—	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,03 ml/kg feed’ 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	7 November 2028

⁽¹⁾ Natural sources of flavourings — Report No 2 (2007)

⁽²⁾ Details of the methods of analysis are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

DECISIONS

COUNCIL DECISION (EU) 2018/1560

of 15 October 2018

establishing the position to be taken on behalf of the European Union within the EPA Committee set up by the stepping stone Economic Partnership Agreement between Côte d'Ivoire, of the one part, and the European Community and its Member States, of the other part, as regards the adoption of a Decision of the EPA Committee concerning the accession of the Republic of Croatia to the European Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union (TFEU), and in particular Articles 207 and 218(9) thereof,

Having regard to the stepping stone Economic Partnership Agreement between Côte d'Ivoire, of the one part, and the European Community and its Member States, of the other part (the 'Agreement') ⁽¹⁾,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Agreement was signed on behalf of the Union on 26 November 2008 pursuant to Council Decision 2009/156/EC ⁽²⁾ and has been applied on a provisional basis since 3 September 2016.
- (2) The Treaty concerning the accession of the Republic of Croatia to the Union was signed on 9 December 2011 and came into force on 1 July 2013.
- (3) The Republic of Croatia acceded to the Agreement on 8 November 2017 by depositing its Act of Accession.
- (4) Pursuant to Article 77 of the Agreement, the EPA Committee may decide on any amending measures which might be necessary following the accession of new Member States to the Union.
- (5) It is appropriate to establish the position to be taken on behalf of the Union with regard to the adoption of a Decision of the EPA Committee, at its annual meeting, regarding the amendments to the Agreement which are necessary following the accession of the Republic of Croatia to the Union,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on behalf of the European Union within the EPA Committee set up by the stepping stone Economic Partnership Agreement between Côte d'Ivoire, of the one part, and the European Community and its Member States, of the other part, as regards the adoption of a Decision of the EPA Committee, during its annual meeting, concerning the accession of the Republic of Croatia to the Union, shall be based on the draft Decision of the EPA Committee attached to this Decision.

⁽¹⁾ OJ L 59, 3.3.2009, p. 3.

⁽²⁾ Council Decision 2009/156/EC of 21 November 2008 on the signature and provisional application of the stepping stone Economic Partnership Agreement between Côte d'Ivoire, of the one part, and the European Community and its Member States, of the other part (OJ L 59, 3.3.2009, p. 1).

Article 2

After its adoption, the Decision of the EPA Committee shall be published in the *Official Journal of the European Union*.

Done at Luxembourg, 15 October 2018.

For the Council
The President
F. MOGHERINI

DRAFT

DECISION No .../2018 OF THE EPA COMMITTEE**set up by the stepping stone Economic Partnership Agreement between Côte d'Ivoire, of the one part, and the European Community and its Member States, of the other part****of ...****concerning the accession of the Republic of Croatia to the European Union**

THE EPA COMMITTEE,

Having regard to the stepping stone Economic Partnership Agreement between Côte d'Ivoire, of the one part, and the European Community and its Member States, of the other part (the 'Agreement'), signed in Abidjan on 26 November 2008, and applied on a provisional basis since 3 September 2016, and in particular Articles 76, 77 and 81 thereof,

Having regard to the Treaty concerning the Accession of the Republic of Croatia to the European Union (the 'Union'), and the Act of Accession to the Agreement deposited by the Republic of Croatia on 8 November 2017,

Whereas:

- (1) The Agreement applies, on the one hand, to the territories in which the Treaty on the Functioning of the European Union is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of Côte d'Ivoire.
- (2) Pursuant to Article 77(3) of the Agreement, the EPA Committee may decide on any amending measures which might be necessary following the accession of new Member States to the Union,

HAS ADOPTED THIS DECISION:

Article 1

The Republic of Croatia, as a Party to the Agreement, shall, in the same manner as the other Member States of the Union, respectively adopt and take note of the text of the Agreement, as well as the Annexes, Protocols and Declarations attached thereto.

Article 2

Article 81 of the Agreement is replaced by the following:

*'Article 81***Authentic texts**

This Agreement is drawn up in duplicate in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, each of these texts being equally authentic.'

Article 3

The Union shall communicate the Croatian language version of the Agreement to Côte d'Ivoire.

Article 4

1. The provisions of the Agreement shall apply to goods exported from either Côte d'Ivoire to the Republic of Croatia or from the Republic of Croatia to Côte d'Ivoire which comply with the rules of origin in force in the territory of the Parties to the Agreement and which, on 3 September 2016, were either in transit or in temporary storage, in a customs warehouse or in a free zone in Côte d'Ivoire or in the Republic of Croatia.
2. Preferential treatment shall be granted in the cases referred to in paragraph 1, provided that a proof of origin issued retroactively by the customs authorities of the exporting country is submitted to the customs authorities of the importing country within four months of the date of entry into force of this Decision.

Article 5

Côte d'Ivoire undertakes not to make any claim, request or referral nor to modify or withdraw any concession pursuant to Article XXIV.6 and Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 or Article XXI of the General Agreement on Trade in Services (GATS) in relation to the accession of the Republic of Croatia to the Union.

Article 6

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

However, Articles 3 and 4 shall apply from 3 September 2016.

Done at ...,

For Côte d'Ivoire

For the European Union

COUNCIL DECISION (EU) 2018/1561**of 15 October 2018**

establishing the position to be taken on behalf of the European Union within the EPA Committee set up by the interim Agreement with a view to an Economic Partnership Agreement between the European Community and its Member States, of the one part, and the Central Africa Party, of the other part, as regards the adoption of a Decision of the EPA Committee concerning the accession of the Republic of Croatia to the European Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union (TFEU), and in particular Articles 207 and 218(9) thereof,

Having regard to the interim Agreement with a view to an Economic Partnership Agreement between the European Community and its Member States, of the one part, and the Central Africa Party, of the other part (the 'Agreement') ⁽¹⁾,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Agreement was signed on behalf of the Union on 15 January 2009 pursuant to Council Decision 2009/152/EC ⁽²⁾ and has been applied on a provisional basis since 4 August 2014.
- (2) The Treaty concerning the accession of the Republic of Croatia to the European Union was signed on 9 December 2011 and came into force on 1 July 2013.
- (3) The Republic of Croatia acceded to the Agreement on 8 November 2017 by depositing its Act of Accession.
- (4) Pursuant to Article 102 of the Agreement, the EPA Committee may decide on any amending measures which might be necessary following the accession of new Member States to the Union.
- (5) It is appropriate to establish the position to be taken on behalf of the Union with regard to the adoption of a Decision by the EPA Committee, at its annual meeting, regarding the amendments to the Agreement which are necessary following the accession of the Republic of Croatia to the Union,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on behalf of the European Union within the EPA Committee set up by the interim Agreement with a view to an Economic Partnership Agreement between the European Community and its Member States, of the one part, and the Central Africa Party, of the other part, as regards the adoption of a Decision of the EPA Committee, during its annual meeting, concerning the accession of the Republic of Croatia to the Union, shall be based on the draft Decision of the EPA Committee attached to this Decision.

Article 2

After its adoption, the Decision of the EPA Committee shall be published in the *Official Journal of the European Union*.

Done at Luxembourg, 15 October 2018.

For the Council

The President

F. MOGHERINI

⁽¹⁾ OJ L 57, 28.2.2009, p. 2.

⁽²⁾ Council Decision 2009/152/EC of 20 November 2008 on the signature and provisional application of the interim agreement with a view to an Economic Partnership Agreement between the European Community and its Member States, of the one part, and the Central Africa Party, of the other part (OJ L 57, 28.2.2009, p. 1).

DRAFT

DECISION No .../2018 OF THE EPA COMMITTEE

set up by the interim Agreement with a view to an Economic Partnership Agreement between the European Community and its Member States, of the one part, and the Central Africa Party, of the other part,

of ...

concerning the accession of the Republic of Croatia to the European Union

THE EPA COMMITTEE,

Having regard to the interim Agreement with a view to an Economic Partnership Agreement between the European Community and its Member States, of the one part, and the Central Africa Party, of the other part, (the 'Agreement'), signed in Brussels on 15 January 2009, and applied on a provisional basis since 4 August 2014, and in particular Articles 100, 102 and 107 thereof,

Having regard to the Treaty concerning the accession of the Republic of Croatia to the European Union (the 'Union'), and the act of accession to the Agreement deposited by the Republic of Croatia on 8 November 2017,

Whereas:

- (1) Under the terms of the Agreement and this Decision, the Central Africa Party is composed of the Republic of Cameroon.
- (2) The Agreement applies, on the one hand, to the territories in which the Treaty on the Functioning of the European Union is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of the Republic of Cameroon.
- (3) Pursuant to Article 102(3) of the Agreement, the EPA Committee may decide on any amending measures which might be necessary following the accession of new Member States to the European Union,

HAS ADOPTED THIS DECISION:

Article 1

The Republic of Croatia, as a Party to the Agreement, shall, in the same manner as the other Member States of the Union, respectively adopt and take note of the text of the Agreement, as well as of the Annexes, Protocols and Declarations attached thereto.

Article 2

Article 107 of the Agreement is replaced by the following:

'Article 107

Authentic texts

This Agreement is drawn up in duplicate in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, each of these texts being equally authentic.'

Article 3

The Union shall communicate the Croatian language version of the Agreement to the Republic of Cameroon.

Article 4

1 The provisions of the Agreement shall apply to goods exported from either the Republic of Cameroon to the Republic of Croatia or from the Republic of Croatia to the Republic of Cameroon, which comply with the rules of origin in force in the territories of the Parties to the Agreement and which, on 4 August 2014, were either in transit or in temporary storage, in a customs warehouse or in a free zone in the Republic of Cameroon or in the Republic of Croatia.

2. Preferential treatment shall be granted in the cases referred to in paragraph 1, provided that a proof of origin issued retroactively by the customs authorities of the exporting country is submitted to the customs authorities of the importing country, within four months of the date of entry into force of this Decision.

Article 5

The Republic of Cameroon undertakes not to make any claim, request or referral nor to modify or withdraw any concession pursuant to Article XXIV.6 and Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 or Article XXI of the General Agreement on Trade in Services (GATS) in relation to the accession of the Republic of Croatia to the European Union.

Article 6

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

However, Articles 3 and 4 shall apply from 4 August 2014.

Done at ...,

For the Republic of Cameroon

For the European Union

