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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/960

of 1 February 2023

amending the regulatory technical standards laid down in Delegated Regulation (EU) 2017/588 as regards the annual application date of the calculations of the average daily number of transactions for shares, depository receipts and exchange-traded funds for the purposes of the tick sizes

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU ⁽¹⁾, and in particular Article 49(3), third subparagraph, thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2017/588 ⁽²⁾ sets out the tick size regime for shares, depository receipts and exchange-traded funds. In accordance with Article 3(1) of that Delegated Regulation, by 1 March each year, the competent authority for a specific share or depository receipt is to publish calculations of the average daily number of transactions for that financial instrument. In accordance with Article 3(4) of that Delegated Regulation, trading venues are to use those calculations to determine the applicable tick size from 1 April following that publication. That date of 1 April each year leads to difficulties for trading venues and their members or participants with regard to the implementation of the required changes to their IT systems and infrastructures. In particular, when 1 April is in the middle of the week, the implementation of the required changes needs to take place overnight. This gives trading venues limited time to update and test their IT systems and infrastructures. It is appropriate to allow trading venues and their members or participants to use the weekend to make the necessary adaptations to their IT systems and infrastructures. The published data should therefore apply from the first Monday of April each year. Such an amendment, in addition, ensures alignment with application of published calculations in accordance with Article 17(2) of Commission Delegated Regulation (EU) 2017/587 ⁽³⁾. Article 17(2) of that Delegated Regulation as amended by Commission Delegated Regulation (EU) 2023/944 ⁽⁴⁾, specifies that calculations on the most relevant market in terms of liquidity, the average daily turnover and the average value of transactions that are published by 1 March, are to apply from the first Monday of April following that publication.

⁽¹⁾ OJ L 173, 12.6.2014, P. 349.

⁽²⁾ Commission Delegated Regulation (EU) 2017/588 of 14 July 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council with regard to regulatory technical standards on the tick size regime for shares, depository receipts and exchange-traded funds (OJ L 87, 31.3.2017, p. 411).

⁽³⁾ Commission Delegated Regulation (EU) 2017/587 of 14 July 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council on markets in financial instruments with regard to regulatory technical standards on transparency requirements for trading venues and investment firms in respect of shares, depository receipts, exchange-traded funds, certificates and other similar financial instruments and on transaction execution obligations in respect of certain shares on a trading venue or by a systematic internaliser (OJ L 87, 31.3.2017, p. 387).

⁽⁴⁾ Commission Delegated Regulation (EU) 2023/944 of 17 January 2023 amending and correcting the regulatory technical standards laid down in Delegated Regulation (EU) 2017/587 as regards certain transparency requirements applicable to transactions in equity instruments (OJ L 131, 16.5.2023, p. 1).

- (2) Delegated Regulation (EU) 2017/588 should therefore be amended accordingly.
- (3) This Regulation is based on the draft regulatory technical standards submitted to the Commission by the European Securities and Markets Authority.
- (4) The European Securities and Markets Authority has conducted open public consultations on the draft regulatory technical standards on which this Regulation is based, analysed the potential related costs and benefits and requested the advice of the Securities and Markets Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1095/2010 of the European Parliament and of the Council ⁽³⁾,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Delegated Regulation (EU) 2017/588

In Article 3 of Delegated Regulation (EU) 2017/588, paragraph 4 is replaced by the following:

‘4. Trading venues shall apply the tick sizes of the liquidity band corresponding to the average daily number of transactions as published in accordance with paragraph 1 from the first Monday of April following that publication.’

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, 1 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84).

COMMISSION IMPLEMENTING REGULATION (EU) 2023/961**of 12 May 2023****amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food Lacto-N-neotetraose****(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 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 of novel foods 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⁾ has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes Lacto-N-neotetraose of synthetic and microbial source as authorised novel food.
- (4) Commission Implementing Decision (EU) 2016/375 ⁽³⁾ authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽⁴⁾, the placing on the market of chemically synthesised Lacto-N-neotetraose as a novel food ingredient.
- (5) Pursuant to Article 5 of Regulation (EC) No 258/97, on 1 September 2016, the company Glycom A/S, notified the Commission of its intention to place on the market Lacto-N-neotetraose of microbial source produced with genetically modified *Escherichia coli* strain K-12 as a novel food ingredient. Lacto-N-neotetraose of microbial origin produced with genetically modified *Escherichia coli* strain K-12 was included in the Union list of novel foods on the basis of that notification when the Union list was established.
- (6) Commission Implementing Regulation (EU) 2019/1314 ⁽⁵⁾ amended the specifications of the novel food Lacto-N-neotetraose (microbial source) produced with genetically modified *Escherichia coli* strain K-12.
- (7) Commission Implementing Regulation (EU) 2021/912 ⁽⁶⁾ amended the specifications of the novel food Lacto-N-neotetraose (microbial source) to allow the novel food Lacto-N-neotetraose produced by the combined activity of the genetically modified strains PS-LNnT-JBT and DS-LNnT-JBT derived from *Escherichia coli* strain BL21(DE3) to be placed on the market and be used in the previously authorised uses and at the previously authorised use levels.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Commission Implementing Decision (EU) 2016/375 of 11 March 2016 authorising the placing on the market of Lacto-N-neotetraose as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 70, 16.3.2016, p. 22).

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

⁽⁵⁾ Commission Implementing Regulation (EU) 2019/1314 of 2 August 2019 authorising the change of the specifications of the novel food Lacto-N-neotetraose produced with *Escherichia coli* K-12 under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 205 5.8.2019, p. 4).

⁽⁶⁾ Commission Implementing Regulation (EU) 2021/912 of 4 June 2021 authorising changes in the specifications of the novel food Lacto-N-neotetraose (microbial source) and amending Implementing Regulation (EU) 2017/2470 (OJ L 199, 7.6.2021, p.10).

- (8) On 3 October 2022, the company Glycom A/S ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change in the conditions of use of Lacto-N-neotetraose. The application requested for Lacto-N-neotetraose to be used in infant formula, follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽⁷⁾, at the currently authorised levels of up to 0,6 g/l, without the obligatory use in combination with 2'-Fucosyllactose at a 1:2 use ratio (one part Lacto-N-neotetraose with two parts 2'-Fucosyllactose), and in milk-based drinks and similar products intended for young children without the obligatory use in combination with 2'-Fucosyllactose at a 1:2 use ratio when the two novel foods are added separately.
- (9) In the application for the proposed modification in the conditions of use of Lacto-N-neotetraose, the applicant considered that obligatory use of a combination of Lacto-N-neotetraose with 2'-Fucosyllactose at a 1:2 ratio when they are used together in infant formula and follow-on formula as defined in Article 2 of Regulation (EU) No 609/2013, or at different ratios with 2'-Fucosyllactose when the two are used in combination in milk-based drinks and similar products intended for young children, unnecessarily limits the ability of food business operators to place on the market these foods with different ratios of those two oligosaccharides.
- (10) The Commission considers that the requested update of the Union list concerning the change in the conditions of use of Lacto-N-neotetraose proposed by the applicant is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. In this regard, the Authority in a recent opinion ⁽⁸⁾ concluded that the use of Lacto-N-neotetraose alone or 2'-Fucosyllactose alone in food supplements as defined in Article 2 of Directive 2002/46/EC of the European Parliament and of the Council ⁽⁹⁾ at the currently maximum authorised levels of up to 0,6 mg/day or up to 1,2 g/day respectively, is safe and the resulting intakes of each of these oligosaccharides from these uses would be lower than the intakes of Lacto-N-neotetraose or 2'-Fucosyllactose from human milk which naturally contains them.
- (11) The information provided in the application and existing Authority's opinions gives sufficient grounds to establish that the changes in the conditions of use of the novel food Lacto-N-neotetraose should be approved.
- (12) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

⁽⁷⁾ 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).

⁽⁸⁾ EFSA Journal 2022; 207(5):7257.

⁽⁹⁾ 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).

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

Done at Brussels, 12 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for lacto-*N*-neotetraose is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Lacto-<i>N</i>-neotetraose	<i>Specified food category</i>	<i>Maximum levels</i>	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'lacto-<i>N</i>-neotetraose'. 2. The labelling of food supplements containing lacto-<i>N</i>-neotetraose shall bear a statement that the supplements should not be used if other foods with added lacto-<i>N</i>-neotetraose are consumed the same day. 3. The labelling of food supplements containing lacto-<i>N</i>-neotetraose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added lacto-<i>N</i>-neotetraose are consumed the same day.'	
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,6 g/l		
	Unflavoured fermented milk-based products	0,6 g/l for beverages		
		9,6 g/kg for products other than beverages		
	Flavoured fermented milk-based products including heat-treated products	0,6 g/l for beverages		
		9,6 g/kg for products other than beverages		
	Dairy analogues, including beverage whiteners	0,6 g/l for beverages		
		6 g/kg for products other than beverages		
		200 g/kg for whitener		
	Cereal bars	6 g/kg		
	Table-top sweeteners	100 g/kg		
	Infant formula as defined under Regulation (EU) No 609/2013	0,6 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	0,6 g/l in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
	Processed cereal-based foods and baby foods for infants and young children as defined under Regulation (EU) No 609/2013	6 g/kg for products other than beverages		
		0,6 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer		

Milk based drinks and similar products intended for young children	0,6 g/l for milk-based drinks and similar products in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer		
Foods 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		
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	2,4 g/l for drinks		
	20 g/kg for bars		
Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	30 g/kg		
Flavoured drinks	0,6 g/l		
Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	4,8 g/l – the maximum level refers to the products ready to use		
Food Supplements as defined in Directive 2002/46/EC, for the general population, excluding infants	1,5 g/day for general population 0,6 g/day for young children		

COMMISSION IMPLEMENTING REGULATION (EU) 2023/962**of 15 May 2023****amending Implementing Regulation (EU) 2021/1448 as regards the conditions of approval of the low-risk active substance calcium carbonate and limestone, and amending 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 13(2)(c) thereof,

Whereas:

- (1) Commission Directive 2008/127/EC ⁽²⁾ included the approval of calcium carbonate and limestone as active substances in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Pursuant to Article 78(3) of Regulation (EC) No 1107/2009, active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009. The approval of the active substance calcium carbonate, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾, was initially set to expire on 31 August 2022. The approval of the active substance limestone, as set out in Part A of the Annex to the same Regulation was set to expire on 31 August 2019.
- (3) Commission Implementing Regulation (EU) 2021/1448 ⁽⁵⁾ renewed the approval of the low-risk active substance calcium carbonate until 31 October 2036 and amended the Annex to Implementing Regulation (EU) No 540/2011 accordingly.
- (4) On 11 August 2017, AgroRadomysl a.s. submitted to Czechia, as rapporteur Member State, an application for the approval of the active substance limestone in accordance with Article 7(1) of Regulation (EC) No 1107/2009.
- (5) On 26 July 2019, the rapporteur Member State notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') of the admissibility of the application, in accordance with Article 9(3) of Regulation (EC) No 1107/2009.
- (6) The rapporteur Member State finalised its assessment, in the form of a draft assessment report, and sent it to the Commission and the Authority on 11 September 2020. The draft assessment report included a recommendation concerning the decision to be taken with regard to the approval of limestone for the representative uses supported by the applicant.

⁽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⁾ 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).

⁽⁴⁾ 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).

⁽⁵⁾ Commission Implementing Regulation (EU) 2021/1448 of 3 September 2021 renewing the approval of the low-risk active substance calcium carbonate 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 (OJ L 313, 6.9.2021, p. 15).

- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (8) On 8 April 2022 ⁽⁶⁾, the Authority communicated to the Commission its conclusion ⁽⁷⁾ on whether limestone can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) In its conclusion, the Authority stated that the two substances, calcium carbonate and limestone, are chemically the same substance.
- (10) The Commission presented a draft review report on limestone (as an additional specification of calcium carbonate) on 8 December 2022 and a draft of this Regulation amending the renewal of approval of calcium carbonate to the Standing Committee on Plants, Animals, Food and Feed on 23 March 2023.
- (11) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 13(1) of Regulation (EC) No 1107/2009, on the draft review report. The applicant submitted its comments, which have been carefully examined.
- (12) Pursuant to Regulation (EC) No 1107/2009, 'substances' should be understood as chemical elements and their compounds, as they occur naturally or by manufacture. Since limestone is composed of calcium carbonate and is chemically the same substance, it is appropriate to include limestone under the same entry as 'calcium carbonate'.
- (13) Calcium carbonate and limestone being chemically the same substance, the Commission considers that the low-risk criteria for calcium carbonate under Article 22 and point 5.1 of Annex II to Regulation (EC) No 1107/2009 are also fully applicable to limestone.
- (14) It is therefore necessary to amend the conditions of approval of calcium carbonate so as to include the specification of limestone. Implementing Regulation (EU) No 540/2011 should 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

Amendment to Implementing Regulation (EU) No 540/2011

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

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*.

⁽⁶⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance limestone. *EFSA Journal* 2022;20(5):7315.

⁽⁷⁾ *EFSA Journal* 2021;19(4):6500. Available online: www.efsa.europa.eu

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

Done at Brussels, 15 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Entry 31 in Part D of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'31	Calcium carbonate CAS No 471-34-1 CIPAC No 843 Limestone CAS No 1317-65-3 CIPAC No 852	IUPAC name: Calcium carbonate	950 g/kg	1 November 2021	31 October 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on calcium carbonate and the review report on limestone, and in particular Appendices I and II thereto, shall be taken into account.'

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

DECISIONS

COUNCIL DECISION (CFSP) 2023/963

of 15 May 2023

appointing the European Union Special Representative for the Gulf region

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 33 and Article 31(2) thereof,

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

Whereas:

- (1) On 18 May 2022, the European Commission and the High Representative of the Union for Foreign Affairs and Security Policy adopted a Joint Communication to the European Parliament and to the Council on a strategic partnership with the Gulf. This was followed by the Council conclusions of 20 June 2022.
- (2) A European Union Special Representative (EUSR) for the Gulf region should be appointed for a period of 21 months.
- (3) The Council and the Commission, assisted by the High Representative of the Union for Foreign Affairs and Security Policy, should ensure consistency between the different areas of the Union's external action in the Gulf region and should cooperate closely to that effect. The EUSR will support and cooperate with the institutions in this respect.
- (4) The EUSR is to implement the mandate in the context of a situation, which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty on European Union,

HAS ADOPTED THIS DECISION:

Article 1

European Union Special Representative

Mr Luigi DI MAIO is hereby appointed as the European Union Special Representative (EUSR) for the Gulf region from 1 June 2023 until 28 February 2025. The Council may decide that the mandate of the EUSR be terminated earlier, on the basis of an assessment by the Political and Security Committee (PSC) and a proposal from the High Representative of the Union for Foreign Affairs and Security Policy (HR).

Article 2

Policy objectives

The mandate of the EUSR shall be consistent with the Union's foreign policy objectives in the Gulf region. Those objectives include:

- (a) safeguarding the Union's fundamental interests and security in the Gulf region;
- (b) promoting good and close relations between the Union and the countries of the Gulf region on the basis of common values and interests;
- (c) building a stronger, comprehensive and more strategic partnership with the countries in the Gulf region to enhance prosperity and security;
- (d) contributing to stability and security in the Gulf region by promoting de-escalation of tensions and supporting dialogue and long-term regional solutions in the Gulf region.

*Article 3***Mandate**

In order to achieve the policy objectives, the mandate of the EUSR shall be to:

- (a) support the HR, together with the European External Action Service (EEAS), in the implementation of the foreign policy and security aspects of the 18 May 2022 Joint Communication on a Strategic Partnership with the Gulf and the related Council conclusions of 20 June 2022;
- (b) contribute through diplomatic channels to the preservation of peace and the prevention of conflicts in the region, as well as the mitigation of their potential effects, in particular by addressing common threats such as terrorism, climate change, environmental degradation or energy insecurity;
- (c) help to ensure consistency of the Union's external action and promote the Union's priorities, values and interests in the region;
- (d) contribute to a better understanding of the role of the Union and its visibility in the region, help to address disinformation and to build stronger people-to-people contacts;
- (e) to strengthen contacts with the Gulf region partners individually, but also by liaising, where required, with relevant regional organisations like the Gulf Cooperation Council, the League of Arab States and other relevant organisations at the EUSR's level;

*Article 4***Implementation of the mandate**

1. The EUSR shall be responsible for the implementation of the mandate, acting under the authority of the HR.
2. The PSC shall maintain a privileged link with the EUSR and shall be the EUSR's primary point of contact with the Council. The PSC shall provide the EUSR with strategic guidance and political direction within the framework of the mandate, without prejudice to the powers of the HR.
3. The EUSR shall work in close coordination with the relevant departments of the EEAS.
4. The EUSR shall work in close coordination with Union Delegations in the region.
5. The EUSR shall be based in the EEAS headquarters, traveling regularly to the region.

*Article 5***Financing**

1. The financial reference amount intended to cover the expenditure related to the mandate of the EUSR for the period from 1 June 2023 until 28 February 2025 shall be EUR 1 800 000.
2. The expenditure shall be managed in accordance with the procedures and rules applicable to the general budget of the Union.
3. The management of the expenditure shall be subject to a contract between the EUSR and the Commission. The EUSR shall be accountable to the Commission for all expenditure.

*Article 6***Constitution and composition of the team**

1. Within the limits of the EUSR's mandate and the corresponding financial means made available, the EUSR shall be responsible for constituting a team. The team shall include expertise on specific policy issues as required by the mandate. The EUSR shall keep the Council and the Commission promptly informed of the composition of the team.

2. Member States, the institutions of the Union and the EEAS may propose the secondment of staff to the EUSR. The salary of such seconded personnel shall be covered by the Member State concerned, the institution of the Union concerned or the EEAS, respectively. Experts seconded by Member States to the institutions of the Union or the EEAS may also be posted to the EUSR's team. International contracted staff shall have the nationality of a Member State.

3. All seconded personnel shall remain under the administrative authority of the sending Member State, the sending institution of the Union or the EEAS and shall carry out their duties and act in the interest of the mandate of the EUSR.

Article 7

Privileges and immunities of the EUSR and the staff of the EUSR

The privileges, immunities and further guarantees necessary for the completion and smooth functioning of the EUSR's mission and the members of the EUSR's staff shall be agreed with the host countries, as appropriate. Member States and the EEAS shall grant all necessary support to such effect.

Article 8

Security of EU classified information

The EUSR and the members of the EUSR's team shall respect the security principles and minimum standards established by Council Decision 2013/488/EU ⁽¹⁾.

Article 9

Access to information and logistical support

1. Member States, the Commission services, the EEAS and the General Secretariat of the Council shall ensure that the EUSR is given access to any relevant information.

2. The Union delegations in the region and/or the Member States, as appropriate, shall provide logistical support in the region.

Article 10

Security

In accordance with the Union's policy on the security of personnel deployed outside the Union in an operational capacity under Title V of the Treaty on European Union, the EUSR shall take all reasonably practicable measures, in accordance with the mandate and the security situation in the geographical area of responsibility, for the security of all personnel under the EUSR's direct authority, in particular by:

- (a) establishing a specific security plan based on guidance from the EEAS, including specific physical, organisational and procedural security measures governing the management of the secure movement of personnel to, and within, the area of responsibility, as well as the management of security incidents, and including a contingency plan and evacuation plan;
- (b) ensuring that all personnel deployed outside the Union are covered by high-risk insurance, as required by the conditions in the area of responsibility;
- (c) ensuring that all members of the EUSR's team to be deployed outside the Union, including locally contracted personnel, have received appropriate security training before or upon arriving in the area of responsibility, based on the risk ratings assigned to that area by the EEAS;

⁽¹⁾ Council Decision 2013/488/EU of 23 September 2013 on the security rules for protecting EU classified information, (OJ L 274, 15.10.2013, p. 1).

- (d) ensuring that all agreed recommendations made following regular security assessments are implemented, and providing the Council, the HR and the Commission with written reports on their implementation and on other security issues within the framework of the regular progress reports and a final comprehensive mandate implementation report.

Article 11

Reporting

The EUSR shall regularly provide the HR, EEAS and the PSC with oral and written reports. The EUSR shall also report to Council working parties, as necessary. Regular reports shall be circulated through the COREU network. The EUSR may provide the Foreign Affairs Council with reports. The EUSR may be involved in briefing the European Parliament.

Article 12

Coordination

1. The EUSR shall contribute to the unity, consistency and effectiveness of the Union's action and shall help ensure that all Union instruments and Member States' actions are engaged consistently, to attain the Union's policy objectives. The activities of the EUSR shall be coordinated with those of the Commission. The EUSR shall provide regular briefings to Member States' missions and Union delegations in the region.
2. In the field, close liaison shall be maintained with the Heads of Union Delegations and Member States' Heads of Mission. They shall make every effort to assist the EUSR in the implementation of the mandate. To that effect, the EUSR shall also liaise with other international and regional actors in the field.

Article 13

Review

The implementation of this Decision and its consistency with other contributions from the Union to the region shall be kept under regular review. The EUSR shall present the Council, the HR and the Commission with regular progress reports and a final comprehensive mandate implementation report by 30 November 2024.

Article 14

Entry into force

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

Done at Brussels, 15 May 2023.

For the Council
The President
J. FORSSMED

COUNCIL DECISION (CFSP) 2023/964**of 15 May 2023****amending Decision (CFSP) 2019/797 concerning restrictive measures against cyber-attacks threatening the Union or its Member States**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

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

Whereas:

- (1) On 17 May 2019, the Council adopted Decision (CFSP) 2019/797 ⁽¹⁾.
- (2) Decision (CFSP) 2019/797 applies until 18 May 2025. On the basis of a review of that Decision, the validity of the restrictive measures set out therein should be extended until 18 May 2024.
- (3) Decision (CFSP) 2019/797 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Article 10 of Decision (CFSP) 2019/797 is replaced by the following:

‘Article 10

This Decision shall apply until 18 May 2025 and shall be kept under constant review. The measures set out in Articles 4 and 5 shall apply as regards the natural and legal persons, entities and bodies listed in the Annex until 18 May 2024.’.

Article 2

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

Done at Brussels, 15 May 2023.

For the Council
The President
J. FORSSMED

⁽¹⁾ Council Decision (CFSP) 2019/797 of 17 May 2019 concerning restrictive measures against cyber-attacks threatening the Union or its Member States (OJ L 129 I, 17.5.2019, p. 13).

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2023/965

of 12 May 2023

on the methodology for the monitoring of food additive and food flavouring intake

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁽¹⁾ lays down the provisions for monitoring food additive intake. In accordance with Article 27 of that Regulation, Member States are to maintain systems to monitor the consumption and use of food additives listed in Annex II, Part B to that Regulation (EC) No 1333/2008 following a risk-based approach and to report their findings with appropriate frequency to the Commission and the European Food Safety Authority ('the Authority'). To this end, the Commission was to adopt a common methodology for the gathering of information by the Member States on dietary intake of food additives in the Union.
- (2) Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁽²⁾ lays down the provisions for monitoring food flavourings intake. In accordance with Article 20 of that Regulation, Member States are to establish systems to monitor, by using a risk-based approach, the consumption and use of flavourings set out in the Union list and the consumption of the substances listed in Annex III to that Regulation (EC) No 1334/2008, and to report their findings with appropriate frequency to the Commission and to the Authority. To this end, the Commission was to adopt a common methodology for the gathering of information by the Member States on dietary intake of food flavouring in the Union.
- (3) While a common methodology is necessary to ensure that the intake of food additives and food flavourings calculated by different Member States may be compared and that the collected data may be used to calculate the intake at Union level, the elaboration of that common methodology is hampered by the limited availability of methods of analysis, analytical standards and the lack of information on the use of food flavourings.
- (4) However, on 23 June 2010 ⁽³⁾ and 23 December 2022 ⁽⁴⁾, the Authority provided guidance for estimating the dietary intake of food flavourings. For food additives, the Authority provided on 18 July 2012 guidance on estimating dietary intake ⁽⁵⁾ and launched at the same time an exposure assessment tool for food additives namely the Food Additive Intake Model (FAIM). On 17 October 2017, the Authority published a statement on the approach

⁽¹⁾ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

⁽²⁾ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

⁽³⁾ EFSA Journal 2010; 8(6):1623.

⁽⁴⁾ EFSA Journal 2022;20(12):7673.

⁽⁵⁾ EFSA Journal 2012;10(7):2760.

followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation ⁽⁶⁾. On the basis of that guidance and in order to gain experience, tackle some of the difficulties encountered and facilitate the adoption of a common methodology in the future, the Commission recommends Member States to apply the methodology provided in this Recommendation.

- (5) Considering the high number of food additives and food flavourings that may be present in different foodstuffs on the market and consequently the high number of potential combinations of food additives and food flavourings with food categories, it is appropriate that Member States categorise and prioritise food additives and food flavourings based on the risk associated to them. In order to ensure an objective prioritisation, the risk should be assessed mainly on the basis of the outcome of the most recent risk assessment by the Authority or the Scientific Committee on Food, of other indications that a food additive or food flavouring needs to be kept under closer surveillance, such as the presence of impurities in case of food additives, or of indications that the dietary intake used for the safety assessment is outdated or underestimated. However, Member States should not categorise and prioritise food flavourings for which the Commission intends to request information from producers and users and those for which monitoring does not appear necessary based on the outcome of the last assessment made by the Authority. Furthermore, in order to ensure flexibility, Member States may adjust the priorities by taking other factors into account.
- (6) In order to ensure the information is available among the Member States, the Commission and the Authority, Member States should reflect the outcome of the prioritisation carried out in a multi-annual monitoring plan and keep the multi-annual monitoring plan updated.
- (7) Since the collected data should allow for the calculation of the food additive and food flavouring intake, the collection of presence data only is not sufficient and Member States should collect at least one type of occurrence data. However, presence data may also be collected since they allow to identify whether a food additive or food flavouring is used or not used in a particular foodstuff.
- (8) In order to ensure that the collected data is representative for the use of the food additive or food flavouring in foods on the market within the Member State and for estimating the intake of those food additives and food flavourings, Member States should decide on the foodstuffs where the presence or occurrence of food additives and food flavourings is to be monitored in accordance with criteria that take into account the relative contribution of foods or brands to the dietary intake. Furthermore, since certain substances, such as ascorbic acid, can occur in food due to natural presence, due to their addition as a nutrient source, or due to their addition as a food additive or food flavouring, Member States should also take into account foods that contribute to the dietary intake of a substance from sources other than its use as food additive or food flavouring, in order to allow for the calculation of the dietary intake from sources other than food additive or food flavouring use and for the calculation of the overall exposure to the concerned substance.
- (9) To obtain a more complete view of the situation, Member States may complement monitoring data with data originating from official control tasks in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council ⁽⁷⁾ that are representative for the use of food additives or food flavourings in food available on the market.

⁽⁶⁾ EFSA Journal 2017;15(10):5042.

⁽⁷⁾ 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') (OJ L 95, 7.4.2017, p. 1).

- (10) In order to obtain reliable results, Member States should use methods of analysis referred to in Article 34 of Regulation (EU) 2017/625, which contains a list of methods used for laboratory analyses.
- (11) Given the diversity of food additives and food flavourings, of the foods in which they are used and of their conditions of use, experience and knowledge gained by Member States may only be compared and assessed if they have been obtained on the same food additives and food flavourings. Therefore, Member States should not only proceed to the prioritisation of food additives and food flavourings and inform the other Member States, the Commission and the Authority, but, as a first stage, they should also agree to monitor at least a common, limited, list of foods additives and flavourings,

RECOMMENDS:

- (1) For the purposes of this Recommendation the following definitions apply:
- (a) 'monitoring of food additive and food flavouring intake' means the collection of data on the presence and occurrence of food additives and food flavourings in food in order to assess the national dietary intake of food additives and food flavourings and verify the occurrence data used and the dietary intake estimated at the time of the most recent exposure assessment by the Authority or the Scientific Committee on Food;
 - (b) 'presence data' means data on the presence or the absence of a specific food additive or food flavouring in a foodstuff;
 - (c) 'occurrence data' means the concentration (expressed as mg/l or mg/kg of food, as appropriate) of the food additive or food flavouring in a foodstuff, which includes actual use levels and analytical data;
 - (d) 'actual use levels' means the concentration of the food additive or food flavouring reported by business operators to be added to food;
 - (e) 'analytical data' means the concentration of the food additive or food flavouring measured in the food;
 - (f) 'reference point' means the dose derived from experimental data that is used in risk assessment to establish a safe level (e.g. an acceptable daily intake) or to explore safety concerns by calculating the margin of exposure in case it is not appropriate to establish a safe level or the available data do not allow to establish a safe level;
 - (g) 'acceptable daily intake' is the estimated maximum amount of an agent, expressed on a body mass basis, to which individuals in a (sub)population may be exposed daily over their lifetimes without appreciable health risk ⁽⁸⁾.
- (2) Member States should categorise food additives and food flavourings in accordance with, respectively, Parts A and C of the Annex. However, food additives that are under re-evaluation or for which the follow-up to the re-evaluation is on-going should not be subject to monitoring.
- (3) Member States should allocate a priority to each food additive and food flavouring, in accordance with Parts B and D of the Annex.

Member States may take other legitimate factors into account, such as the dual use as food additive and food flavouring, the availability of analytical methods and standards, public concern, a particular high or low use of a specific food additive or food flavouring in their territory, frequent consumption by specific population groups, or the lack of information on the foods in which a flavour might have been used.

- (4) Member States should by 30 September 2025:
- (a) categorise and prioritise food additives;

⁽⁸⁾ EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760. [53 pp.] doi:10.2903/j.efsa.2012.2760.

(b) categorise and prioritise:

- food flavourings belonging to group 1, 2 and 4, as defined in Part C of the Annex;
- the substances from group 3, as defined in Part C of the Annex, for which a reference point has been identified and an intake assessment is available.

From 2026, Member States should update the categorisation and prioritisation on a yearly basis, taking the outcome from the monitoring of the previous year and new risk assessments published by the Authority into account.

- (5) Member States should prepare a multi-annual monitoring plan reflecting the outcome of the prioritisation. This multi-annual monitoring plan should cover at least three years and should list the food additives and food flavourings to be monitored each year. It should be updated on a yearly basis, taking the updated categorisation and prioritisation into account.
- (6) Member States should collect at least one of the following types of data:
- (a) actual use levels at national level, in the case of food additives;
 - (b) analytical data.
- Member States may also collect presence data.
- (7) Member States should decide on the foodstuffs where the occurrence of a food additive or food flavouring is to be monitored taking into account the following aspects:
- (a) the food categories in which the presence of a food additive or food flavouring can be expected;
 - (b) the food categories assumed to be significant contributors to the food additive and food flavouring intake for the whole population or specific age groups;
 - (c) the main brands consumed;
 - (d) foods that can contribute to dietary intake from sources other than food additive or food flavouring use.
- (8) Member States can complement monitoring data with data originating from official control tasks in accordance with Regulation (EU) 2017/625, if the latter are representative for the use of food additives or food flavouring in food available on the market. When using data originating from official control tasks, Member States should only use data from the planned control programme, and should not use data from follow-up incidents.
- (9) Member States should carry out the monitoring activities for food additives and food flavourings with appropriate methods of analysis that have been proven to generate reliable results. Methods used for laboratory analyses should comply with Article 34 of Regulation (EU) 2017/625. As a minimum requirement for the monitoring of food additive and food flavouring intake, Member States should consider the use of a method validated with an inter- or intra-laboratory method validation study in accordance with internationally accepted scientific protocols.
- (10) Where it is not possible to analyse the food flavouring in the final food Member States should analyse formulations, preparations or intermediate products. However, Member States should calculate the corresponding concentration of the food flavouring in the final food in order to allow for the calculation of the dietary intake of the food flavouring.
- (11) Member States should provide the collected data to the Authority on a yearly basis, together with the information specified by the Authority and in the electronic format as set out by the Authority.

Member States should report to the Authority and the Commission on a yearly basis:

- (a) the outcome of the prioritisation;
- (b) the multi-annual monitoring plan;

- (c) the applied methodology, in particular, where relevant, how the actual use levels and presence data were obtained and whether data originating from official control tasks were used to complement the monitoring data;
 - (d) whether non-authorised uses were identified.
- (12) Member States should organise a pilot phase and to this end:
- (a) propose to the other Member States and the Commission by April 2023 a list of five food additives and five food flavourings;
 - (b) agree on a list of five food additives and five food flavourings;
 - (c) collect data during the year 2024 for three of the food additives and two of the food flavourings included in the agreed list and report the data collected by 30 June 2025 to the Authority;
 - (d) collect data during the year 2025 for two of the food additives and three of the food flavourings included in the agreed list and report the data collected by June 2026 to the Authority.

Done at Brussels, 12 May 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

Risk-based categorisation and prioritisation of food additives and food flavourings for monitoring

PART A: Food additive categorisation

Food additives should be categorised into three groups:

1. **Group 1: Food additives with an ‘acceptable daily intake not specified’ or for which the Authority or the Scientific Committee on Food has concluded in the most recent risk assessment that ‘there is no need for a numerical acceptable daily intake’**
 - 1a. food additives with no particular concern;
 - 1b. food additives which need to be kept under closer surveillance due to the presence of impurities or due to another reason.
2. **Group 2: Food additives for which the Authority or the Scientific Committee on Food has set in the most recent risk assessment numerical acceptable daily intakes**
 - 2a. Food additives with no safety concern identified in the most recent risk assessment on the basis of maximum permitted levels or food additives for which the Authority calculated in the most recent risk assessment refined intake estimates not exceeding 50 % of the acceptable daily intake for any of the age groups.
 - 2b. Food additives for which the Authority calculated in the most recent risk assessment refined intake estimates exceeding 50 % of the acceptable daily intake for at least one age group.
 - 2c. Food additives not included in points 2a or 2b which need to be kept under closer surveillance due to the presence of impurities or due to another reason.
3. **Group 3: Food additives for which the Authority concluded that there would be no safety concern despite missing data to establish a numerical acceptable daily intake**
 - 3a. Food additives for which the Authority indicated that there would be no safety concern at the reported uses and use levels despite missing data to establish a numerical acceptable daily intake and which do not need to be kept under closer surveillance.
 - 3b. Food additives for which the Authority indicated that there would be no safety concern at the reported uses and use levels despite missing data to establish a numerical acceptable daily intake but need to be kept under closer surveillance due to the presence of impurities or due to another reason.

PART B: Food additive prioritisation

Food additives should be classified into three levels of priority:

1. **High priority**

Food additives from Group 2b for which there are indications that the dietary intake as assessed in the most recent risk assessment is outdated or underestimated.
2. **Medium priority**
 - 2.1 Food additives from Group 2b not covered under high priority.
 - 2.2 Food additives from Group 2a for which there are indications that the dietary intake as assessed in the most recent risk assessment is outdated or underestimated.
 - 2.3 Food additives from Group 3a for which there are indications that the dietary intake as assessed in the most recent risk assessment is outdated or underestimated.
 - 2.4 Food additives from Group 2c

2.5 Food additives from Group 3b

2.6 Food additives from Group 1b

3. Low priority

3.1 Food additives from Group 1a

3.2 Food additives from Group 2a not covered under medium priority

3.3 Food additives from Group 3a not covered under medium priority

PART C: Food flavouring categorisation

Food flavourings should be categorised into four groups:

Group 1: Undesirable substances included in Annex III to Regulation (EC) No 1334/2008.

Group 2: Smoke flavourings as authorised by Commission Implementing Regulation (EU) No 1321/2013 ⁽¹⁾.

Group 3: Food flavourings authorised for use with or without restrictions in accordance with Annex I to Regulation (EC) No 1334/2008 and for which the modified theoretical added maximum daily intake (mTAMDI) as calculated by the Authority in the most recent risk assessment exceeds the threshold of toxicological concern ⁽²⁾ value established by the Authority.

Group 4: Food flavourings and food ingredients with flavouring properties not covered by groups 1 to 3.

PART D: Food flavouring prioritisation

Food flavourings should be classified into three levels of priority

1. High priority

1.1 Food flavourings belonging to group 3 for which all the following conditions are met:

- (a) a reference point has been identified and intake assessment is available;
- (b) there are indications that the dietary intake as assessed in the most recent risk assessment is outdated or underestimated;
- (c) a doubling of the intake would pose a health concern.

1.2 Undesirable substances belonging to group 1.

1.3 Food flavourings which might also be present in flavouring preparations, and which have been removed from the union list of flavouring substances due to safety concerns.

2. Medium priority

2.1 Food flavourings belonging to group 3 for which no reference point has been identified. Within this group, substances that exceed the threshold of toxicological concern value more should be monitored first.

2.2 Substances belonging to group 2 (smoke flavourings).

⁽¹⁾ Commission Implementing Regulation (EU) No 1321/2013 of 10 December 2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings (OJ L 333, 12.12.2013, p. 54).

⁽²⁾ Threshold of toxicological concern values have been established for substances of similar chemical structure and likelihood of toxicity, based on extensive published toxicological data. There are three broad categories of low, moderate or high toxicity (EFSA Journal 2019;17(6):5708).

3. Low priority

- 3.1 Food flavourings belonging to group 3 not covered under the high or medium priority.
 - 3.2 Flavourings and food ingredients with flavouring properties belonging to group 4 not covered under the high priority.
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