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⁽¹⁾ Text with EEA relevance.

EN

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2018/977

of 4 April 2018

correcting the Bulgarian language version of Delegated Regulation (EU) 2017/653 supplementing Regulation (EU) No 1286/2014 of the European Parliament and of the Council on key information documents for packaged retail and insurance-based investment products (PRIIPs) by laying down regulatory technical standards with regard to the presentation, content, review and revision of key information documents and the conditions for fulfilling the requirement to provide such documents

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1286/2014 of the European Parliament and of the Council of 26 November 2014 on key information documents for packaged retail and insurance-based investment products (PRIIPs) ⁽¹⁾, and in particular Article 8(5), Article 10(2) and Article 13(5) thereof,

Whereas:

- (1) The Bulgarian language version of Commission Delegated Regulation (EU) 2017/653 ⁽²⁾ contains an error in Annex II, Part 2, point 51 as regards the number of classes by which the CRM are increased.
- (2) The Bulgarian language version of Delegated Regulation (EU) 2017/653 should therefore be corrected accordingly. The other language versions are not affected,

HAS ADOPTED THIS REGULATION:

Article 1

(does not concern the English language)

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*.

⁽¹⁾ OJ L 352, 9.12.2014, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2017/653 of 8 March 2017 supplementing Regulation (EU) No 1286/2014 of the European Parliament and of the Council on key information documents for packaged retail and insurance-based investment products (PRIIPs) by laying down regulatory technical standards with regard to the presentation, content, review and revision of key information documents and the conditions for fulfilling the requirement to provide such documents (OJ L 100, 12.4.2017, p. 1).

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

Done at Brussels, 4 April 2018.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION REGULATION (EU) 2018/978**of 9 July 2018****amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products****(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 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products ⁽¹⁾, and in particular Article 31(1) thereof,

Whereas:

- (1) *Tagetes erecta*, *Tagetes minuta* and *Tagetes patula* extracts and oils are widely used fragrance ingredients of many fragrance compounds used in perfumery. The Scientific Committee on Consumer Products (SCCP), subsequently replaced by the Scientific Committee on Consumer Safety (SCCS), concluded in its opinion of 21 June 2005 ⁽²⁾ that *Tagetes erecta*, *Tagetes minuta* and *Tagetes patula* extracts and oils should not be used in cosmetic products as no safe limits had been demonstrated.
- (2) Following the submission in August 2013 of an update dossier on the safety assessment of *Tagetes minuta* and *Tagetes patula* extracts and oils, the SCCS adopted a revised opinion on 25 March 2015 ⁽³⁾. In that opinion, as corrected on 13 December 2017 ⁽⁴⁾, the SCCS concluded that for *Tagetes minuta* and *Tagetes patula* extracts and oils in leave-on products (except sunscreen products and products marketed for exposure to natural/artificial UV light), a maximum concentration in ready to use preparation of 0,01 % is safe, provided that the alpha terthienyl (terthiophene) content of those extracts and oils does not exceed 0,35 %. The SCCS thus concluded that *Tagetes minuta* and *Tagetes patula* extracts and oils should not be used as ingredients in sunscreen products and in products marketed for exposure to natural/artificial UV light.
- (3) In a comment of 6 October 2016 ⁽⁵⁾ to its opinion of 25 March 2015, the SCCS indicated that for *Tagetes minuta* and *Tagetes patula* extracts and oils in rinse-off products, a maximum concentration in ready to use preparation of 0,1 % should be set.
- (4) In light of the opinion of the SCCP of 21 June 2005 there is a potential risk to human health arising from the use of *Tagetes erecta* flower extract and *Tagetes erecta* flower oil in cosmetic products. Those substances should therefore be prohibited in cosmetic products and added in the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009.
- (5) In light of the opinion of the SCCP of 21 June 2005, the revised opinion of the SCCS of 25 March 2015, as corrected on 13 December 2017, and the comment of the SCCS of 6 October 2016, there is a potential risk to human health arising from the use of *Tagetes minuta* and *Tagetes patula* flower extracts and flower oils in cosmetic products in a concentration exceeding 0,01 % in leave-on products and 0,1 % in rinse-off products and from the use of those extracts and oils in a leave-on or rinse-off product where the content of alpha terthienyl (terthiophene) in the extracts or oils exceeds 0,35 %. There is also a potential risk to human health arising from the use of *Tagetes minuta* and *Tagetes patula* flower extracts and flower oils in any concentration in sunscreen products and products marketed for exposure to natural/artificial UV light. Those substances should therefore be added in the list of restricted substances in Annex III to Regulation (EC) No 1223/2009.
- (6) It is appropriate to provide for reasonable periods of time in order for the industry to adapt to the new prohibitions and restrictions. The complex and lengthy procedure for fragrance reformulation should be reflected in a longer than usual duration of the time periods given to the industry for adjustments of products.

⁽¹⁾ OJ L 342, 22.12.2009, p. 59.

⁽²⁾ SCCP/0869/05; https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_025d.pdf;

⁽³⁾ SCCS/1551/15; https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_172.pdf

⁽⁴⁾ SCCS/1551/15; https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_172.pdf

⁽⁵⁾ Minutes of the SCCS Plenary of 6 October 2016; https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs2016_mi_plenary_02_en.pdf

- (7) Annexes II and III to Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (8) The measure provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II and III to Regulation (EC) No 1223/2009 are amended in accordance with the Annex to this Regulation.

Article 2

From 1 May 2019 cosmetic products containing one or more of the substances prohibited by this Regulation and cosmetic products containing one or more of the substances restricted by this Regulation and not complying with the restrictions laid down in this Regulation shall not be placed on the Union market.

From 1 August 2019 cosmetic products containing one or more of the substances prohibited by this Regulation and cosmetic products containing one or more of the substances restricted by this Regulation and not complying with the restrictions laid down in this Regulation shall not be made available on the Union market.

Article 3

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, 9 July 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annexes II and III are amended as follows:

(1) in Annex II, in the table, the following entry is added:

Ref No.	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
'x	Tagetes erecta flower extract (*)	90131-43-4	290-353-9
	Tagetes erecta flower oil (**)	90131-43-4	290-353-9/-

(*) From 1 May 2019 cosmetic products containing that substance shall not be placed on the Union market. From 1 August 2019 cosmetic products containing that substance shall not be made available on the Union market.

(**) From 1 May 2019 cosmetic products containing that substance shall not be placed on the Union market. From 1 August 2019 cosmetic products containing that substance shall not be made available on the Union market.'

(2) in Annex III, in the table, the following entries are added:

Reference number	Substance Identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
'x	Tagetes minuta flower extract (*)	Tagetes minuta flower extract	91770-75-1;	294-862-7;	(a) Leave-on products	(a) 0,01 %	For (a) and (b): Alpha terthienyl (terthiophen) content in the extract/oil ≤ 0,35 %. For (a): Not to be used in sunscreen products and products marketed for exposure to natural/artificial UV light. For (a) and (b): In case of combined use with Tagetes patula (entry x), the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (g).	
	Tagetes minuta flower oil (**)	Tagetes minuta flower oil	91770-75-1/ 8016-84-0	294-862-7	(b) Rinse-off products	(b) 0,1 %		

Reference number	Substance Identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
x	Tagetes patula flower extract (***)	Tagetes patula flower extract	91722-29-1; 91722-29-1/ 8016-84-0	294-431-3; 294-431-3/-	(a) Leave-on products	(a) 0,01 %	For (a) and (b): Alpha terthienyl (terthiophen) content in the extract/oil ≤ 0,35 %. For (a): Not to be used in sunscreen products and products marketed for exposure to natural/artificial UV light. For (a) and (b): In case of combined use with Tagetes minuta (entry x), the total combined content of Tagetes in ready for use preparation shall not exceed the maximum concentration limits set out in column (g).	
	Tagetes patula flower oil (****)	Tagetes patula flower oil			(b) Rinse-off products	(b) 0,1 %		

(*) From 1 May 2019 cosmetic products containing that substance and not complying with the restrictions shall not be placed on the Union market. From 1 August 2019 cosmetic products containing that substance and not complying with the restrictions shall not be made available on the Union market.

(**) From 1 May 2019 cosmetic products containing that substance and not complying with the restrictions shall not be placed on the Union market. From 1 August 2019 cosmetic products containing that substance and not complying with the restrictions shall not be made available on the Union market.

(***) From 1 May 2019 cosmetic products containing that substance and not complying with the restrictions shall not be placed on the Union market. From 1 August 2019 cosmetic products containing that substance and not complying with the restrictions shall not be made available on the Union market.

(****) From 1 May 2019 cosmetic products containing that substance and not complying with the restrictions shall not be placed on the Union market. From 1 August 2019 cosmetic products containing that substance and not complying with the restrictions shall not be made available on the Union market.'

COMMISSION IMPLEMENTING REGULATION (EU) 2018/979**of 11 July 2018****amending Council Regulation (EC) No 1210/2003 concerning certain specific restrictions on economic and financial relations with Iraq**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1210/2003 of 7 July 2003 concerning certain specific restrictions on economic and financial relations with Iraq and repealing Regulation (EC) No 2465/96 ⁽¹⁾, and in particular Article 11(b) thereof,

Whereas:

- (1) Annex III to Regulation (EC) No 1210/2003 lists public bodies, corporations and agencies and natural and legal persons, bodies and entities of the previous government of Iraq covered by the freezing of funds and economic resources that were located outside Iraq on the date of 22 May 2003 under that Regulation.
- (2) On 5 July 2018, the Sanctions Committee of the United Nations Security Council decided to remove one entry from the list of persons or entities to whom the freezing of funds and economic resources should apply,
- (3) Annex III to Regulation (EC) No 1210/2003 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1210/2003 is amended as set out 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, 11 July 2018.

For the Commission,

On behalf of the President,

Head of the Service for Foreign Policy Instruments

⁽¹⁾ OJ L 169, 8.7.2003, p. 6.

ANNEX

In Annex III to Regulation (EC) No 1210/2003, the following entry is deleted:

- '44. GENERAL ESTABLISHMENT FOR GRAIN TRADING (alias (a) GRAIN BOARD OF IRAQ; (b) STATE ORGANISATION OF GRAIN). Addresses: (a) P.O. Box 329, Bab Al Mouadham-Midan, Baghdad, Iraq; (b) P.O. Box 2261, Allque, Irkheta, Karada Al-Shakira, Baghdad, Iraq.'
-

COMMISSION IMPLEMENTING REGULATION (EU) 2018/980**of 11 July 2018****amending Implementing Regulation (EU) No 815/2012, as regards the information to be exchanged between Member States to identify taxable persons using the non-Union scheme**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EU) No 904/2010 of 7 October 2010 on administrative cooperation and combating fraud in the field of value added tax ⁽¹⁾ and in particular Article 44(1), the second subparagraph of Article 44(2), Article 45(1) and (2), and Article 51(1) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 815/2012 ⁽²⁾ lays down detailed rules for the application of Regulation (EU) No 904/2010, in particular as regards the transmission of registration information of taxable persons using special schemes for telecommunications services, broadcasting services or electronic services provided for in Chapter 6 of Title XII of Council Directive 2006/112/EC ⁽³⁾.
- (2) Following the amendment of Articles 358a and 361 of Directive 2006/112/EC by Council Directive (EU) 2017/2455 ⁽⁴⁾, taxable persons not established in the Community who are identified for value added tax (VAT) purposes within the Community will be able as of 1 January 2019 to use the special scheme, set out in Section 2 of Chapter 6 of Title XII of Directive 2006/112/EC (the 'non-Union scheme'), for telecommunications services, broadcasting services or electronic services supplied to non-taxable persons who are established in a Member State or have their permanent address or usually reside in a Member State.
- (3) The common electronic message for the transmission of information to identify taxable persons using the non-Union scheme set out in column B of the table in Annex I to Implementing Regulation (EU) No 815/2012 should therefore be amended accordingly.
- (4) For reasons of consistency, this Regulation should apply from the same date as the provisions of Directive (EU) 2017/2455 introducing the possibility for taxable persons not established in the Community who are identified for VAT purposes within the Community to use the special scheme.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Administrative Cooperation,

HAS ADOPTED THIS REGULATION:

Article 1

In column B of the table in Annex I to Implementing Regulation (EU) No 815/2012, the text in box number 16 is replaced by the following:

'Electronic declaration that the taxable person is not established within the Union'.

*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2019.

⁽¹⁾ OJ L 268, 12.10.2010, p. 1.⁽²⁾ Commission Implementing Regulation (EU) No 815/2012 of 13 September 2012 laying down detailed rules for the application of Council Regulation (EU) No 904/2010, as regards special schemes for non-established taxable persons supplying telecommunications, broadcasting or electronic services to non-taxable persons (OJ L 249, 14.9.2012, p. 3).⁽³⁾ Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (OJ L 347, 11.12.2006, p. 1).⁽⁴⁾ Council Directive (EU) 2017/2455 of 5 December 2017 amending Directive 2006/112/EC and Directive 2009/132/EC as regards certain value added tax obligations for supplies of services and distance sales of goods (OJ L 348, 29.12.2017, p. 7).

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

Done at Brussels, 11 July 2018.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/981**of 11 July 2018****amending the list of Brazilian establishments from which imports into the Union of fishery products intended for human consumption are permitted****(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 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ⁽¹⁾, and in particular Article 12(4)(c) thereof,

Whereas:

- (1) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin. In particular, Article 12(1) of that Regulation provides that, with the exception of certain specific cases, products of animal origin are to be imported into the Union only if they originate from third country establishments that appear on lists drawn up and updated in accordance with that Article. Those lists can be consulted on the website of the Directorate-General for Health and Food Safety ⁽²⁾.
- (2) Article 12(2) of Regulation (EC) No 854/2004 requires that third country establishments are placed on those lists only if the competent authorities of the third country guarantee that those establishments, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, comply with relevant Union requirements. In addition, in accordance with Article 12(3) of Regulation (EC) No 854/2004, the competent authorities of the third country concerned should keep those lists of establishments updated and communicate them accordingly to the Commission.
- (3) Article 15(2)(a) of Regulation (EC) No 854/2004 provides that fishery products imported from a factory or freezer vessel flying the flag of a third country are to come from vessels that appear on a list drawn up and updated in accordance with the procedure set out in Article 12(4) of that Regulation.
- (4) In September 2017, a Commission inspection revealed that primary production establishments supplying Brazilian establishments from which imports of fishery products are permitted are neither identified, nor subject to official controls. Consequently, that audit concluded that the competent authority in Brazil is neither in the position to provide the guarantees set out in Article 12(2)(a) and (b) of Regulation (EC) No 854/2004, nor to provide all the guarantees referred to in the health certificate for fishery products laid down in Appendix IV to Annex VI to Commission Regulation (EC) No 2074/2005 ⁽³⁾. Moreover, that inspection revealed serious deficiencies with regard to infrastructure and hygiene requirements in a number of inspected Brazilian establishments from which imports of fishery products are permitted. The aforesaid deficiencies have shown a systemic lack of effective controls by the Brazilian competent authorities with regard to fishery products.
- (5) In reply to the recommendations made in the preliminary inspection report, the Brazilian authorities informed the Commission, in an official letter dated 22 December 2017, that they have suspended the issuance of health certificates for all fishery products intended for export to the Union as of 3 January 2018. However, Member States notified the Commission that consignments of fishery products originating from Brazil were presented at the Union borders with certificates issued after the date of suspension.

⁽¹⁾ OJ L 139, 30.4.2004, p. 206.

⁽²⁾ https://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en

⁽³⁾ Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ L 338, 22.12.2005, p. 27).

- (6) In light of these considerations, and in the absence of new information from the Brazilian authorities, there are no sufficient guarantees that any of the establishments authorised to export fishery products from Brazil to the Union fulfil the conditions of Article 12(2) of Regulation (EC) No 854/2004 and their products therefore constitute a risk for public health. It is therefore appropriate to remove all establishments from the list of Brazilian establishments from which fishery products intended for human consumption can be imported into the Union.
- (7) In light of the risk to public health associated with their products, those establishments should cease to be authorised to export to the Union without delay. It is therefore appropriate that the date of entry into force of this Regulation is the date following that of its publication.
- (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

The list of establishments referred to in Article 12 of Regulation (EC) No 854/2004 shall be amended in order to remove all entries of Brazilian establishments from which imports into the Union of fishery products for human consumption are permitted.

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, 11 July 2018.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/982**of 11 July 2018****concerning the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as feed additive for chickens for fattening and chickens reared for laying (holder of the authorisation Novus Europe N.A./S.V.)****(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 the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for chickens for fattening, chickens reared for laying, minor avian species for fattening and reared for laying. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for chickens for fattening, chickens reared for laying, minor avian species for fattening and reared for laying, to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 2 December 2014 ⁽²⁾ and 28 September 2017 ⁽³⁾ that, under the proposed conditions of use, the preparation of benzoic acid, calcium formate and fumaric acid does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that it has the potential to improve the performance of chickens for fattening and this conclusion can be extended to chickens reared for laying. However, since no conclusions can be drawn on the margin of safety of the additive for major target species, the conclusions on safety cannot be extrapolated to minor avian species for fattening and to minor avian species reared for laying. 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 the preparation of benzoic acid, calcium formate and fumaric acid 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.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an 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 2015;13(5):3794.

⁽³⁾ EFSA Journal 2017;15(10):5025.

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, 11 July 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improving zootechnical performance)									
4d14	Novus Europe N.A./S.V.	Preparation of benzoic acid, calcium formate and fumaric acid	<p><i>Additive composition</i></p> <p>Preparation of benzoic acid, calcium formate and fumaric acid having a minimum content of:</p> <p>Benzoic acid: 42,5-50 %</p> <p>Calcium formate: 2,5-3,5 %</p> <p>Fumaric acid: 0,8-1,2 %</p> <p>Granulated form</p> <p><i>Characterisation of the active substance</i></p> <p>benzoic acid CAS number: 65-85-0 (≥ 99,0 % purity); C₇H₆O₂</p> <p>calcium formate: CAS number 544-17-2; C₂H₂O₄Ca;</p> <p>fumaric acid (≥ 99,5 % purity): CAS number 110-17-8; C₄H₄O₄.</p> <p><i>Analytical method</i> (1)</p> <p>For the determination of benzoic acid, calcium formate and fumaric acid in the feed additive:</p> <p>— high performance liquid chromatography with UV detection (HPLC-UV)</p>	Chickens for fattening Chickens reared for laying	—	500	1 000	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall not be used with other sources of benzoic acid or benzoates, calcium formate or formate and fumaric acid. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks concerning 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 breathing protection. 	1 August 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
			<p>For the determination of total calcium in the feed additive:</p> <ul style="list-style-type: none"> — atomic absorption spectrometry (AAS) – EN ISO 6869; or — inductively coupled plasma atomic emission spectrometry (ICP-AES) – EN 15510 <p>For the determination of benzoic acid in premixtures and feedingstuffs:</p> <ul style="list-style-type: none"> — high performance liquid chromatography with UV detection (HPLC-UV) <p>For the determination of calcium formate and fumaric acid in premixtures:</p> <ul style="list-style-type: none"> — ion-exclusion high performance liquid chromatography with UV or refractive index detection (HPLC-UV/RI) 						

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

COMMISSION IMPLEMENTING REGULATION (EU) 2018/983**of 11 July 2018****concerning the authorisation of benzoic acid as a feed additive for minor porcine species for fattening and for reproduction (holder of authorisation DSM Nutritional Products Sp. z o. o.)****(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 benzoic acid as a feed additive for minor porcine species for fattening and for reproduction. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of benzoic acid as a feed additive for minor porcine species for fattening and for reproduction, to be classified in the additive category 'zootechnical additives'.
- (4) That additive was already authorised as a feed additive for use in weaned piglets by Commission Regulation (EC) No 1730/2006 ⁽²⁾, in pigs for fattening by Commission Regulation (EC) No 1138/2007 ⁽³⁾ and in sows by Commission Implementing Regulation (EU) 2016/900 ⁽⁴⁾.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 September 2017 ⁽⁵⁾ that, under the proposed conditions of use, the benzoic acid does not have an adverse effect on human health or the environment, and that it has a potential to decrease urinary pH in minor porcine species. However, due to the lack of margin of safety in weaned major piglets, the Authority could not extrapolate the conclusion on the safety to weaned minor porcine species. Therefore it was established the additive is safe for minor porcine species for fattening and for reproduction. 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 benzoic acid 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 additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 1730/2006 of 23 November 2006 concerning the authorisation of benzoic acid (VevoVital) as a feed additive (OJ L 325, 24.11.2006, p. 9).

⁽³⁾ Commission Regulation (EC) No 1138/2007 of 1 October 2007 concerning the authorisation of a new use of benzoic acid (VevoVital) as a feed additive (OJ L 256, 2.10.2007, p. 8).

⁽⁴⁾ Commission Implementing Regulation (EU) 2016/900 of 8 June 2016 concerning the authorisation of benzoic acid as a feed additive for sows (holder of authorisation DSM Nutritional Products Ltd) (OJ L 152, 9.6.2016, p. 18).

⁽⁵⁾ EFSA Journal 2017;15(10):5026.

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, 11 July 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (urinary pH decrease).									
4d210	DSM Nutritional Products Sp. z o. o.	Benzoic acid	<p><i>Additive composition:</i></p> <p>Benzoic acid (≥ 99,9 %)</p> <p><i>Characterisation of the active substance:</i></p> <p>Benzenecarboxylic acid, phenylcarboxylic acid,</p> <p>C₇H₆O₂</p> <p>CAS number 65-85-0</p> <p>Maximum level of the impurities:</p> <p>Phthalic acid: ≤ 100 mg/kg</p> <p>Biphenyl: ≤ 100 mg/kg</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>For the quantification of benzoic acid in the feed additive:</p> <p>— titration with sodium hydroxide (European Pharmacopoeia monograph 0066)</p>	Minor porcine species for fattening and for reproduction	—	5 000	5 000	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated..</p> <p>2. The additive shall not be used with other sources of benzoic acid or benzoates.</p> <p>3. The directions of use shall be indicated the following in complementary feed: 'Complementary feedingstuffs containing benzoic acid shall not be fed to minor porcine species for fattening and for reproduction as such'. Complementary feedingstuffs for sows shall be thoroughly mixed with other feed materials of the daily ration'.</p>	1 August 2028

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			<p>For the quantification of the benzoic acid in the premixtures and feedingstuffs:</p> <p>— reversed phase liquid chromatography with UV detection (RP-HPLC/UV) — method based on ISO9231:2008</p>					<p>4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks concerning 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 and skin protection.</p>	

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

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2018 OF THE EU-REPUBLIC OF MOLDOVA ASSOCIATION COUNCIL

of 3 May 2018

as regards the amendment of Annex XXVI to the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part [2018/984]

THE EU-REPUBLIC OF MOLDOVA ASSOCIATION COUNCIL,

Having regard to the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part, and in particular Article 436(3) thereof,

Whereas:

- (1) The Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part ⁽¹⁾ (the 'Agreement') was signed on 27 June 2014.
- (2) Article 201 of the Agreement provides for the gradual approximation to the Union's customs law and certain international law to be carried out as set out in Annex XXVI to the Agreement.
- (3) Annex XXVI to the Agreement specifies that approximation with the provisions of Council Regulation (EEC) No 2913/92 ⁽²⁾ is to be carried out by the Republic of Moldova within three years following the entry into force of the Agreement.
- (4) Regulation (EEC) No 2913/92 has been repealed and, since 1 May 2016, the substantive provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council ⁽³⁾ are in application in the Union.
- (5) At the meeting of the EU-Republic of Moldova Customs Sub-Committee held on 6 October 2016, it was concluded that Annex XXVI to the Agreement should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex XXVI to the Agreement is amended as set out in the Annex to this Decision.

Article 2

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

Done at Brussels, 3 May 2018.

For the Association Council

The Chair

F. MOGHERINI

⁽¹⁾ OJ L 260, 30.8.2014, p. 4.

⁽²⁾ Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).

⁽³⁾ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

ANNEX

The first section of Annex XXVI to the Agreement is amended as follows:

The reference 'Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code' is replaced by the reference 'Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code'.

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