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⁽¹⁾ Text with EEA relevance.

EN

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

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II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2021/2043

of 18 November 2021

on the conclusion, on behalf of the Union, of the Sustainable Fisheries Partnership Agreement between the European Union, of the one part, and the Government of Greenland and the Government of Denmark, of the other part, and the implementing Protocol thereto

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43 in conjunction with Article 218(6), second subparagraph, point (a)(v) and Article 218(7) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament ⁽¹⁾,

Whereas:

- (1) On 9 December 2019 the Council authorised the Commission to open negotiations with the Government of Greenland and the Government of Denmark with a view to concluding a new sustainable fisheries partnership agreement and a new implementing protocol thereto.
- (2) The negotiations were successfully concluded with the initialling of the Sustainable Fisheries Partnership Agreement between the European Union, of the one part, and the Government of Greenland and the Government of Denmark, of the other part ('the Partnership Agreement') and the Protocol implementing the Sustainable Fisheries Partnership Agreement between the European Union, of the one part, and the Government of Greenland and the Government of Denmark, of the other part ('the Protocol') on 11 January 2021.
- (3) The Partnership Agreement repeals the Fisheries Partnership Agreement between the European Community on the one hand, and the Government of Denmark and the Home Rule Government of Greenland, on the other hand ⁽²⁾, which entered into force on 28 June 2007.
- (4) In accordance with Council Decision (EU) 2021/793 ⁽³⁾, the Partnership Agreement and the Protocol were signed on 22 April 2021.
- (5) The Partnership Agreement and the Protocol have been applied on a provisional basis since the date of their signature.
- (6) The Partnership Agreement and the Protocol should be approved.

⁽¹⁾ Consent of 5 October 2021 (not yet published in the Official Journal).

⁽²⁾ OJ L 172, 30.6.2007, p. 4.

⁽³⁾ Council Decision (EU) 2021/793 of 26 March 2021 on the signing, on behalf of the European Union, and provisional application of the Sustainable Fisheries Partnership Agreement between the European Union, of the one part, and the Government of Greenland and the Government of Denmark, of the other part, and the implementing Protocol thereto (OJ L 175, 18.5.2021, p. 1).

- (7) Article 12 of the Partnership Agreement establishes the Joint Committee responsible for monitoring its implementation. Furthermore, pursuant to that Article and to Article 4 and Article 7 of the Protocol, the Joint Committee can adopt certain modifications to the Protocol. In order to facilitate the approval of such modifications, the Commission should be authorised, subject to specific substantive and procedural conditions, to approve them on behalf of the Union under a simplified procedure.
- (8) The Union's position on proposed modifications to the Protocol should be established by the Council. The proposed modifications should be approved unless a blocking minority of Member States in accordance with Article 16(4) of the Treaty on European Union objects to those modifications,

HAS ADOPTED THIS DECISION:

Article 1

The Sustainable Fisheries Partnership Agreement between the European Union, of the one part, and the Government of Greenland and the Government of Denmark, of the other part ('the Partnership Agreement') and the Protocol implementing the Sustainable Fisheries Partnership Agreement between the European Union, of the one part, and the Government of Greenland and the Government of Denmark, of the other part ('the Protocol') are hereby approved on behalf of the Union ⁽⁴⁾.

Article 2

The President of the Council shall, on behalf of the Union, give the notification provided for in Article 20 of the Partnership Agreement and the notification provided for in Article 14 of the Protocol.

Article 3

In accordance with the procedure and conditions laid down in the Annex to this Decision, the Commission is hereby authorised to approve, on behalf of the Union, modifications to the Protocol adopted by the Joint Committee established under Article 12 of the Partnership Agreement.

Article 4

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

Done at Brussels, 18 November 2021.

For the Council
The President
Z. ČERNÁČ

⁽⁴⁾ The texts of the Partnership Agreement and of the Protocol are published in OJ L 175 of 18 May 2021.

ANNEX

PROCEDURE AND CONDITIONS FOR THE APPROVAL OF MODIFICATIONS TO THE PROTOCOL TO BE ADOPTED BY
THE JOINT COMMITTEE

Where the Joint Committee is asked to adopt modifications to the Protocol in accordance with Article 12 of the Partnership Agreement and Articles 4 and 7 of the Protocol, the Commission shall be authorised to approve the proposed modifications on behalf of the Union, under the following conditions:

- (1) The Commission shall ensure that the approval on behalf of the Union:
 - (a) is in accordance with the objectives of the common fisheries policy;
 - (b) is consistent with the relevant rules adopted by regional fisheries management organisations and takes account of joint management by coastal States;
 - (c) takes account of the latest statistical, biological and other relevant information sent to the Commission.
- (2) Before the Commission approves proposed modifications on behalf of the Union, the Commission shall submit them to the Council in sufficient time before the relevant Joint Committee meeting.
- (3) The compliance of the proposed modifications with the criteria laid down in point (1) shall be assessed by the Council.
- (4) Unless a number of Member States equivalent to a blocking minority of the Council in accordance with Article 16(4) of the Treaty on European Union object to the proposed modifications, the Commission shall approve them on behalf of the Union. If there is such a blocking minority, the Commission shall reject the proposed modifications on behalf of the Union.
- (5) If, in the course of subsequent meetings of the Joint Committee, it is impossible to reach an agreement, including on the spot, the matter shall be referred back to the Council, in accordance with the procedure set out in points (2) to (4), in order for the Union position to take account of new factors.
- (6) The Commission is invited to take, in due time, any steps necessary to follow up on the decision of the Joint Committee, including, where appropriate, publication of the relevant decision in the *Official Journal of the European Union* and submission of any proposal necessary for the implementation of that decision.

As regards other matters which do not concern modifications to the Protocol in accordance with Article 12 of the Partnership Agreement and Articles 4 and 7 of the Protocol, the position to be adopted by the Union in the Joint Committee shall be determined in accordance with the Treaties and established working practices.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2044

of 17 November 2021

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Nostrano Valtrompia' (PDO))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Italy's application for the approval of amendments to the specification for the protected designation of origin 'Nostrano Valtrompia', registered under Commission Implementing Regulation (EU) No 629/2012 ⁽²⁾.
- (2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ⁽³⁾ as required by Article 50(2)(a) of that Regulation.
- (3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Nostrano Valtrompia' (PDO) are hereby approved.

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 343, 14.12.2012, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 629/2012 of 06 July 2012 entering a name in the register of protected designations of origin and protected geographical indications [Nostrano Valtrompia (PDO)] (OJ L 182, 13.7.2012, p. 12).

⁽³⁾ OJ C 313, 5.8.2021, p. 18.

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

Done at Brussels, 17 November 2021.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

COMMISSION REGULATION (EU) 2021/2045**of 23 November 2021****amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)****(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ⁽¹⁾, and in particular Articles 58 and 131 thereof,

Whereas:

- (1) The substances bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) are listed in entries 4 to 7 of Annex XIV to Regulation (EC) No 1907/2006 because they meet the criteria set out in point (c) of Article 57 of that Regulation. In accordance with Article 59 of Regulation (EC) No 1907/2006, DEHP has subsequently been additionally identified as meeting the criteria set out in point (f) Article 57 of that Regulation, namely as having endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment ⁽²⁾. All the four substances have further been identified in accordance with Article 59 of Regulation (EC) No 1907/2006 as meeting the criteria set out in point (f) Article 57 of that Regulation, namely as having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health ⁽³⁾. In accordance with Article 58(3) of Regulation (EC) No 1907/2006, on 10 July 2019 the European Chemicals Agency ('the Agency') recommended ⁽⁴⁾ the elements referred to in Article 58(1) of that Regulation to be specified for each of those substances.
- (2) The inclusion of intrinsic properties relating to hazards for the environment in the entry for DEHP in Annex XIV to Regulation (EC) No 1907/2006, means that the uses of that substance in medical devices falling within the scope of Council Directive 90/385/EEC ⁽⁵⁾, Council Directive 93/42/EEC ⁽⁶⁾ or Directive 98/79/EC of the European Parliament and of the Council ⁽⁷⁾ are subject to authorisation requirement as the second subparagraph of Article 60(2) of Regulation (EC) No 1907/2006 provides that the Commission shall not consider risks to human health only arising from those uses. As regards the uses of that substance in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁽⁸⁾, the inclusion of intrinsic properties relating to hazards for the environment means that those uses are subject to authorisation requirement as Article 56(5) of Regulation (EC) No 1907/2006 no longer applies to them.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ Decision by the Executive Director of ECHA of 12 December 2014, Inclusion of Substances of Very High Concern in the Candidate List for eventual inclusion in Annex XIV, (ED/108/2014) <https://echa.europa.eu/documents/10162/30b654ce-1de3-487a-8696-e05617c3173b>

⁽³⁾ Commission Implementing Decision (EU) 2017/1210 of 4 July 2017 on the identification of bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) as substances of very high concern according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (OJ L 173, 6.7.2017, p. 35).

⁽⁴⁾ Recommendation of the European Chemicals Agency of 10 July 2019 to amend the Annex XIV entries to REACH of DEHP, BBP, DBP and DIBP (List of Substances subject to Authorisation), https://echa.europa.eu/documents/10162/13640/axiv_amend_recommendation_phthalates_july2019_en.pdf/1889866a-bec3-fe16-6322-67c16a13b09d

⁽⁵⁾ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

⁽⁶⁾ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

⁽⁷⁾ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

⁽⁸⁾ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

- (3) By including in the entries of DEHP, BBP, DBP and DIBP intrinsic properties referred to in point (f) of Article 57 of Regulation (EC) No 1907/2006, the concentration limit applicable to the presence of those substances in mixtures for the purposes of the exemption set out in Article 56(6) of that Regulation becomes 0,1 % weight by weight.
- (4) Article 58(1)(e) in conjunction with Article 58(2) of Regulation (EC) No 1907/2006 provides for the possibility of exemptions of uses or categories of uses in cases where specific Union legislation imposes minimum requirements relating to the protection of human health or the environment ensuring proper control of the risks. In accordance with the information currently available, it is not appropriate to set exemptions based on those provisions.
- (5) Commission Regulation (EU) No 143/2011 ⁽⁹⁾ exempted from the authorisation requirement the use of DEHP, BBP and DBP in the immediate packaging of medicinal products covered by Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽¹⁰⁾, Directive 2001/82/EC of the European Parliament and of the Council ⁽¹¹⁾ and/or Directive 2001/83/EC of the European Parliament and of the Council ⁽¹²⁾. The judgment of the Court of Justice of 13 July 2017 in Case C-651/15 P, *VECCO and Others v. Commission* ⁽¹³⁾, provided clarifications on certain aspects of Article 58(2) of Regulation (EC) No 1907/2006 for granting an exemption from the authorisation requirement. The Commission has re-assessed the exemption set out in Annex XIV to that Regulation and has concluded that it does not meet the conditions in Article 58(2). In particular, in the light of that judgement, Regulation (EC) No 726/2004, and Directives 2001/82/EC and 2001/83/EC do not constitute existing specific Union legislation imposing minimum requirements relating to the protection of human health or the environment for the use of DEHP, BBP and DBP in immediate packaging of medicinal products within the meaning of Article 58(2) of Regulation No 1907/2006 since they do not contain provisions specific to those substances imposing such requirements. Furthermore, Regulation (EC) No 726/2004 and Directives 2001/82/EC and 2001/83/EC lay down requirements related to the protection of human health only, while, as regards DEHP, intrinsic properties relating to hazards for the environment have been included in the entry for that substance in Annex XIV to Regulation (EC) No 1907/2006. Those exemptions are therefore not justified and should be deleted.
- (6) For the uses of DEHP, BBP, DBP and DIBP that will no longer be exempted from the authorisation requirement, it is appropriate to indicate the dates referred to in point (i) of Article 58(1)(c) of Regulation (EC) No 1907/2006, taking into account the Agency's recommendation of 10 July 2019 and its capacity to handle applications for authorisations. As regards uses of DEHP in medical devices, the dates should also take into account the transitional provisions for the application of Regulations (EU) 2017/745 ⁽¹⁴⁾ and (EU) 2017/746 ⁽¹⁵⁾ of the European Parliament and of the Council.
- (7) For each of the uses of DEHP, BBP, DBP and DIBP that will no longer be exempted from the authorisation requirement, there are no reasons for which the date referred to in point (ii) of Article 58(1)(c) of Regulation (EC) No 1907/2006 should be set earlier than 18 months than the date referred to in Article point (i) 58(1)(c) of that Regulation.

⁽⁹⁾ Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') (OJ L 44, 18.2.2011, p. 2).

⁽¹⁰⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

⁽¹¹⁾ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

⁽¹²⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

⁽¹³⁾ Judgment of the Court of Justice of 13 July 2017, *Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-Verbindungen in der Oberflächentechnik eV (VECCO) and Others v European Commission*, C-651/15 P, ECLI:EU:C:2017:543.

⁽¹⁴⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁽¹⁵⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

- (8) During the public consultation conducted by the Agency on its draft recommendation, no specific comments were submitted with regard to possible exemptions for product and process orientated research and development. As there is no information justifying the need for such an exemption, the exemption was not considered.
- (9) As the available information on the uses of the substances concerned by this Regulation is limited, it is not appropriate to set review periods at this stage, pursuant to point (d) of Article 58(1) of Regulation (EC) No 1907/2006.
- (10) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XIV to Regulation (EC) No 1907/2006 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*.

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

Done at Brussels, 23 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

Entries 4 to 7 in the table in Annex XIV to Regulation (EC) No 1907/2006 are replaced by the following entries:

Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses	Review periods
			Latest application date ⁽¹⁾	Sunset date ⁽²⁾		
4.	Bis(2-ethylhexyl) phthalate (DEHP) EC No: 204-211-0 CAS No: 117-81-7	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) – human health) Endocrine disrupting properties (Article 57(f) – environment)	(a) 21 August 2013 (*) (b) By way of derogation from point (a): 14 June 2023 for uses in: — food contact materials within the scope of Regulation (EC) No 1935/2004; — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; — mixtures containing DEHP at or above 0,1 % and below 0,3 % weight by weight; (c) By derogation of point (a): 27 November 2023 for uses in medical devices within the scope of Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	(a) 21 February 2015 (**) (b) By way of derogation from point (a): 14 December 2024 for uses in: — food contact materials within the scope of Regulation (EC) No 1935/2004; — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; — mixtures containing DEHP at or above 0,1 % and below 0,3 % weight by weight; (c) By derogation of point (a): 27 May 2025 for uses in medical devices within the scope of Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	-	-
5.	Benzyl butyl phthalate (BBP) EC No: 201-622-7 CAS No: 85-68-7	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) – human health)	(a) 21 August 2013 (*) (b) By way of derogation from point (a): 14 June 2023 for uses in: — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; — mixtures containing BBP at or above 0,1 % and below 0,3 % weight by weight.	(a) 21 February 2015 (**) (b) By way of derogation from point (a): 14 December 2024 for uses in: — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; — mixtures containing BBP at or above 0,1 % and below 0,3 % weight by weight.	-	-

6.	Dibutyl phthalate (DBP) EC No: 201-557-4 CAS No: 84-74-2	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) – human health)	(a) 21 August 2013 (*) (b) By way of derogation from point (a): 14 June 2023 for uses in: — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; — mixtures containing DBP at or above 0,1 % and below 0,3 % weight by weight.	(a) 21 February 2015 (**) (b) By way of derogation from point (a): 14 December 2024 for uses in: — immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC; — mixtures containing DBP at or above 0,1 % and below 0,3 % weight by weight.	-	-
7.	Diisobutyl phthalate (DIBP) EC No: 201-553-2 CAS No: 84-69-5	Toxic for reproduction (category 1B) Endocrine disrupting properties (Article 57(f) – human health)	(a) 21 August 2013 (*) (b) By way of derogation from point (a): 14 June 2023 for uses in mixtures contain- ing DIBP at or above 0,1 % and below 0,3 % weight by weight.	(a) 21 February 2015 (**) (b) By way of derogation from point (a): 14 December 2024 for uses in mixtures containing DIBP at or above 0,1 % and below 0,3 % weight by weight.	-	-

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2046

of 23 November 2021

granting protection in the Union to the Geographical Indication 'ម្សរៀង កំពត'/'Kampot Pepper' registered in the International Register of Appellations of Origin and Geographical Indications of the Geneva Act

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/1753 of the European Parliament and of the Council of 23 October 2019 on the action of the Union following its accession to the Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications ⁽¹⁾, and in particular Article 7(1) thereof,

Whereas:

- (1) In accordance with Article 5(1) and (2) of the Geneva Act, the Competent Authorities of each Contracting Party to the Geneva Act may file applications for international registration of an appellation of origin or geographical indication with the International Bureau of the World Intellectual Property Organization, which registers it in the International Register in accordance with Article 6 of the Geneva Act. In accordance with Article 9 of the Geneva Act, the other Contracting Parties shall protect registered appellations of origin and geographical indications within their own legal system subject to any refusal, renunciation, invalidation or cancellation.
- (2) In accordance with Article 6(4) of the Geneva Act, on 14 December 2020, the International Bureau of the World Intellectual Property Organization notified the Commission that the name 'ម្សរៀង កំពត'/'Kampot Pepper', applied by Cambodia, had been recorded as Geographical Indication in the International Register of Appellations of Origin and Geographical Indications under the Geneva Act.
- (3) Pursuant to Article 4(1) of Regulation (EU) 2019/1753, the international registration of the Geographical Indication 'ម្សរៀង កំពត'/'Kampot Pepper' was published in the *Official Journal of the European Union* ⁽²⁾ to enable possible opposition to be lodged.
- (4) Pursuant to Article 5 of Regulation (EU) 2019/1753, the Commission assessed the international registration of the Geographical Indication 'ម្សរៀង កំពត'/'Kampot Pepper' against the conditions laid down in that Article and concluded that they are fulfilled.
- (5) As no opposition under Article 6 of Regulation (EU) 2019/1753 has been received by the Commission, the name 'ម្សរៀង កំពត'/'Kampot Pepper' should be protected in the Union, in accordance with the Geneva Act.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Agricultural Product Quality Policy Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'ម្សរៀង កំពត'/'Kampot Pepper', registered as Geographical Indication in the International Register, shall be protected in the Union.

The name referred to in the first paragraph identifies a product of the type 'pepper'.

⁽¹⁾ OJ L 271, 24.10.2019, p. 1.

⁽²⁾ OJ C 30, 27.1.2021, p. 9.

Article 2

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

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

Done at Brussels, 23 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2047**of 23 November 2021****concerning the authorisation of amprolium hydrochloride (COXAM) as a feed additive for chickens for fattening and chickens reared for laying (holder of authorisation: HuvePharma NV)****(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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of amprolium hydrochloride (COXAM). That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The application concerns the authorisation of amprolium hydrochloride (COXAM) as a feed additive for chickens for fattening and chickens reared for laying, to be classified in the additive category 'coccidiostats and histomonostats'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 13 June 2018 ⁽²⁾ and 27 January 2021 ⁽³⁾ that, under the proposed conditions of use, the amprolium hydrochloride (COXAM) does not have an adverse effect on animal health and the environment. It also concluded that the additive should be considered a potential respiratory and skin sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that it cannot independently evaluate all data relevant to the current application due to the lack of provided data and is therefore unable to conclude on the safety of the additive for the consumer. The Authority further concluded that the additive is efficacious in controlling coccidiosis in chickens for fattening, and that this conclusion is extended to chickens reared for laying. The Authority also concluded that a post-market monitoring plan to monitor the *Eimeria* spp. resistance should be undertaken. 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) Amprolium hydrochloride has already been evaluated by the European Medicines Agency Committee for Medicinal Products for Veterinary Use (EMA CVMP). In its report from January 2001 ⁽⁴⁾, EMA CVMP concluded that there is no need to establish a maximum residue limit (MRL) for amprolium. Therefore amprolium for poultry is listed in Table 1 of the Annex to Commission Regulation (EC) No 37/2010 ⁽⁵⁾. On these grounds, the safety of amprolium hydrochloride for the consumer has been sufficiently demonstrated according to Article 8(4)(e) of Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2018;16(7):5338.

⁽³⁾ EFSA Journal 2021;19(3):6457.

⁽⁴⁾ EMA CVMP (European Medicines Agency Committee for Medicinal Products for Veterinary Use), 2001. Amprolium Summary Report (2). EMEA/MRL/767/00-FINAL. January 2001. https://www.ema.europa.eu/en/documents/mrl-report/amprolium-summary-report-2-committee-veterinary-medicinal-products_en.pdf

⁽⁵⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

- (6) The assessment of amprolium hydrochloride (COXAM) 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 substance should be authorised.
- (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

Authorisation

The substance specified in the Annex, belonging to the additive category 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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, 23 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of additive	Name of the holder 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 %			
Additive category: coccidiostats and histomonostats									
51777	HuvePharma NV	Amprolium hydrochloride (COXAM)	Additive composition Amprolium HCl: 250 g/kg Liquid paraffin: 30 g/kg Rice hulls q.s. to 1,000 g. Characterisation of the active substance Amprolium hydrochloride (> 97,5 % purity) C ₁₄ H ₁₉ ClN ₄ .HCl, (1-[(4-amino-2-propyl-5-pyrimidinyl)methyl]-2-methylpyridinium chloride monohydrochloride, CAS Number: 137-88-2 Related impurities: 2-picoline < 0,52 % sulfated ash ≤ 0,1 % Analytical method ⁽¹⁾ For the quantification of amprolium in the feed additive: — Reversed-Phase High Performance Liquid Chromatography using Ultraviolet detection at 268 nm (RP-HPLC-UV). For the quantification of amprolium in premixtures and feedingstuffs:	Chickens for fattening Chickens reared for laying	-	125	125	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 be incorporated in compound feed in the form of a premixture. 3. The additive shall not be mixed with other coccidiostats. 4. Post-market monitoring programmes shall be carried out by the holder of authorisation for: resistance to bacteria and <i>Eimeria</i> spp.	14.12.2031

			— Cation exchange High Performance Liquid Chromatography using Ultraviolet detection at 264 nm (IE-HPLC-UV) – Regulation (EC) No 152/2009.					5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks of 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 skin and breathing protection.	
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(¹) <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

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