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Contents

[1] Text with EEA relevance.

EN

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

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

[1] Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2018/121

of 23 January 2018

amending Regulation (EU) No 560/2014 establishing the Bio-based Industries Joint Undertaking

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 187 and the first paragraph of Article 188 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament ([1]),

Having regard to the opinion of the European Economic and Social Committee ([2]),

Whereas:

(1) Council Regulation (EU) No 560/2014 ([3]) established the Bio-based Industries Joint Undertaking ('BBI Joint Undertaking').

(2) Article 12(4) of the Statutes of the BBI Joint Undertaking, set out in the Annex to Regulation (EU) No 560/2014 ('the Statutes'), states that the financial contribution by the members of the BBI Joint Undertaking other than the Union to operational costs is to be at least EUR 182 500 000 over the period provided for in Article 1 of Regulation (EU) No 560/2014, that is to say from the establishment of the BBI Joint Undertaking until 31 December 2024.

(3) The Bio-based Industries Consortium Aisbl ('BIC'), which is a member of the BBI Joint Undertaking other than the Union, continues to be ready to support the operational costs of the BBI Joint Undertaking for the amount set out in Article 12(4) of the Statutes. It has however proposed an alternative mode of financing through financial contributions made by its constituent entities at the indirect actions' level.

(4) The objective of the Joint Technology Initiative on Bio-based Industries to carry out activities through the collaboration of stakeholders along the entire bio-based value chain, including small and medium-sized enterprises, research and technology centres and universities can be achieved only by enabling BIC and its constituent entities to deliver the financial contribution not only as payments to the BBI Joint Undertaking but also as financial contributions to indirect actions funded by the BBI Joint Undertaking.

(5) It is therefore necessary to amend the Statutes in order to enable BIC and its constituent entities to deliver the financial contribution for the full amount set out in Article 12(4) of the Statutes, allowing those contributions to be made not only as payments to the BBI Joint Undertaking but also as financial contributions to indirect actions funded by the BBI Joint Undertaking and to be reported to the BBI Joint Undertaking,

([1]) Opinion of the European Parliament of 24 October 2017 (not yet published in the Official Journal).
([2]) Opinion of the European Economic and Social Committee of 27 April 2017 (not yet published in the Official Journal).
([3]) Council Regulation (EU) No 560/2014 of 6 May 2014 establishing the Bio-based Industries Joint Undertaking (OJ L 169, 7.6.2014, p. 130).

HAS ADOPTED THIS REGULATION:

Article 1

Article 12 of the Statutes of the Bio-based Industries Joint Undertaking, as set out in the Annex to Regulation (EU) No 560/2014, is amended as follows:

(1) in paragraph 3, point (b) is replaced by the following:

'(b) financial contributions by the members other than the Union or their constituent entities;';

(2) paragraph 4 is replaced by the following:

'4. The financial contributions by the members other than the Union or their constituent entities to the operational costs referred to in paragraph 3(b) shall be at least EUR 182 500 000 over the period provided for in Article 1 of this Regulation.

These financial contributions shall be made as payments to the BBI Joint Undertaking or as financial contributions to indirect actions funded by the BBI Joint Undertaking.'.

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 January 2018.

For the Council
The President
V. GORANOV

COMMISSION DELEGATED REGULATION (EU) 2018/122

of 20 October 2017

amending Annexes I, II, VI, VIII and IX to Regulation (EU) No 1007/2011 of the European Parliament and of the Council on textile fibre names and related labelling and marking of the fibre composition of textile products

(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 1007/2011 of the European Parliament and of the Council of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC of the European Parliament and of the Council ([1]), and in particular Article 21 thereof,

Whereas:

(1) Regulation (EU) No 1007/2011 requires labelling to indicate the fibre composition of textile products, with checks being carried out by analysis on the conformity of those products through indications given on the label.

(2) In accordance with Article 6 of Regulation (EU) No 1007/2011, a manufacturer submitted to the Commission an application to include 'polyacrylate' as a new textile fibre name in the list set out in Annex I to that Regulation. That application included a technical file fulfilling all the minimum requirements specified in Annex II to that Regulation.

(3) After having assessed the application for the new textile fibre name and having carried out a public consultation on the Europa website, the Commission, in consultation with Member States' experts and interested parties, concluded that the new textile fibre name 'polyacrylate' should be added to the list of textile fibre names set out in Annex I to Regulation (EU) No 1007/2011.

(4) In order to take into account technical progress, Annex II to Regulation (EU) No 1007/2011 should be amended, in particular as regards the proposed definition of a new textile fibre name and the proposed identification and quantification methods.

(5) Regulation (EU) No 1007/2011 sets out a list of textile products for which inclusive labelling is sufficient. That list includes sewing, mending and embroidery yarns presented for retail sale in small quantities with a net weight of 1 gram or less. However, due to technical progress, that particular textile product is no longer presented for retail sale in quantities with a net weight of 1 gram or less. Therefore, the list of textile products qualifying for inclusive labelling set out in Annex VI to that Regulation should be updated.

(6) In order to make it possible to use uniform methods for quantitative analysis of textile fibre mixtures, test methods set out in Annex VIII to Regulation (EU) No 1007/2011 should be amended to include 'polyacrylate' fibre. Furthermore, a new test method for quantitative analysis of fibre mixtures of polyester and certain other fibres should be added to Annex VIII to that Regulation.

(7) Regulation (EU) No 1007/2011 also lays down the agreed allowances used to calculate the mass of fibres contained in a textile product. Hence, the value of agreed allowance for 'polyacrylate' should be added to the list set out in Annex IX to that Regulation.

(8) Regulation (EU) No 1007/2011 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I, II, VI, VIII and IX to Regulation (EU) No 1007/2011 are amended in accordance with the Annex to this Regulation.

([1]) OJ L 272, 18.10.2011, p. 1.

Article 2

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

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

Done at Brussels, 20 October 2017.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Annexes I, II, VI, VIII and IX to Regulation (EU) No 1007/2011 are amended as follows:

(1) in Annex I, the following row 50 is added:

'50	polyacrylate	fibre formed of cross-linked macromolecules having more than 35 % (by mass) of acrylate groups (acid, light metal salts or esters) and less than 10 % (by mass) of acrylonitrile groups in the chain and up to 15 % (by mass) of nitrogen in the cross-linking';

(2) in Annex II, the following points are amended as follows:

(a) points (2) and (3) are replaced by the following:

'(2) Proposed definition of the textile fibre:

The definition proposed shall describe the fibre composition. The characteristics mentioned in the definition of the new textile fibre, such as elasticity, shall be verifiable via standard test methods to be provided with the technical file along with the experimental results of analyses.

(3) Identification of the textile fibre: chemical formula, differences from existing textile fibres, FTIR spectrum together with, where relevant, detailed data such as melting point, density, refractive index and burning behaviour.';

(b) point (5) is replaced by the following:

'(5) Proposed identification and quantification methods, including experimental data:

The applicant shall evaluate the possibility to use the methods listed in Annex VIII or the harmonised standards to be introduced in that Annex to analyse the most expected commercial mixtures of the new textile fibre with other textile fibres and shall propose at least one of those methods. For those methods or harmonised standards where the textile fibre can be considered as an insoluble component, the applicant shall indicate the 'd' factors, which correspond to the mass correction factors to be applied for the calculations (to account for the loss in mass, known to occur during the analysis) of the new textile fibre.

If methods listed in this Regulation are not suitable, the applicant shall provide adequate reasoning and propose one or more new methods. The proposed new method or methods shall describe the field of application (including fibre mixtures), the principle (notably chemical process and steps), the apparatus and reagent or reagents, the test procedure, the calculation and expression of results (including the value of 'd' factors), and the precision (confidence limits of results).

The application shall contain all the experimental data, in particular regarding fibre characteristics, identification and quantification methods proposed. Data on the accuracy, robustness and repeatability of the methods shall be provided with the file.';

(c) point (7) is replaced by the following:

'(7) Additional information on production process and consumer relevance to support the application:

The technical file shall, at least, contain information on the number of producers, the location of production facilities and the expected market availability of the new fibre or of products manufactured from that fibre.';

(d) the following point (8) is added:

'(8) Availability of samples:

The manufacturer or any person acting on the manufacturer's behalf shall provide representative samples of the new pure textile fibre and the relevant textile fibre mixtures necessary for verifying the accuracy, robustness and repeatability of the proposed identification and quantification methods. The Commission may request additional samples of relevant fibre mixtures from the manufacturer or the person acting on the manufacturer's behalf.';

(3) in Annex VI, item 18 is replaced by the following:

'18. Sewing, mending and embroidery yarns presented for retail sale';

(4) in Annex VIII, chapter 2 is amended as follows:

(a) in the Summary Table of point IV, the following row for method No 17 is added:

'17	Polyester	Certain other fibres	Trichloroacetic acid and chloroform';

(b) method No 1 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), flax (7) true hemp (8), jute (9), abaca (10), alfa (11), coir (12), broom (13), ramie (14), sisal (15), cupro (21), modal (22), protein (23), viscose (25), acrylic (26), polyamide or nylon (30), polyester (35), polypropylene (37), elastomultiester (45), elastolefin (46), melamine (47), polypropylene/polyamide bicomponent (49) and polyacrylate (50).

In no circumstances is the method applicable to acetate fibres which have been deacetylated on the surface.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of 'd' is 1,00, except for melamine and polyacrylate, for which 'd' is 1,01.';

(c) point 1.2 of method No 5 is replaced by the following:

'2. triacetate (24), polypropylene (37), elastolefin (46), melamine (47), polypropylene/polyamide bicomponent (49) and polyacrylate (50).';

(d) point 1.2 of method No 6 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), cupro (21), modal (22), viscose (25), acrylic (26), polyamide or nylon (30), polyester (35), polypropylene (37), glass fibre (44), elastomultiester (45), elastolefin (46), melamine (47), polypropylene/polyamide bicomponent (49) and polyacrylate (50).

Note:

Triacetate fibres which have received a finish leading to partial hydrolysis cease to be completely soluble in the reagent. In such cases, the method is not applicable.';

(e) method No 8 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), cupro (21), modal (22), viscose (25), polyamide or nylon (30), polyester (35), polypropylene (37), elastomultiester (45), elastolefin (46), melamine (47), polypropylene/polyamide bicomponent (49) and polyacrylate (50).

It is equally applicable to acrylics, and certain modacrylics, treated with pre-metallised dyes, but not to those dyed with afterchrome dyes.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of 'd' is 1,00, except in the case of wool, cotton, cupro, modal, polyester, elastomultiester, melamine and polyacrylate, for which 'd' is 1,01.';

(f) method No 9 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), cupro (21), modal (22), viscose (25), acrylic (26), polyamide or nylon (30), polyester (35), polypropylene (37), glass fibre (44), elastomultiester (45), melamine (47), polypropylene/polyamide bicomponent (49) and polyacrylate (50).

When the wool or silk content of the mixture exceeds 25 %, method No 2 shall be used.

When the polyamide or nylon content of the mixture exceeds 25 %, method No 4 shall be used.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of 'd' is 1,00, except for melamine and polyacrylate, for which 'd' is 1,01.';

(g) method No 13 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), acetate (19), cupro (21), modal (22), triacetate (24), viscose (25), acrylic (26), polyamide or nylon (30), polyester (35), glass fibre (44), elastomultiester (45), melamine (47) and polyacrylate (50).';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of 'd' is 1,00, except for melamine and polyacrylate, for which 'd' is 1,01.';

(h) method No 15 is amended as follows:

(i) point 1.2 is replaced by the following:

'2. wool (1), animal hair (2 and 3), silk (4), cotton (5), cupro (21), modal (22), viscose (25), acrylic (26), polyamide or nylon (30), glass fibre (44), melamine (47) and polyacrylate (50).

Where modacrylics or elastanes are present, a preliminary test shall first be carried out to determine whether the fibre is completely soluble in the reagent.

Mixtures containing chlorofibres may also be analysed by using method No 9 or 14.';

(ii) point 5 is replaced by the following:

'5. CALCULATION AND EXPRESSION OF RESULTS

Calculate the results as described in the general instructions. The value of 'd' is 1,00, except in the case of polyacrylate, for which 'd' is 1,02, silk and melamine, for which 'd' is 1,01, and acrylic, for which 'd' is 0,98.';

(i) the following method is added:

'METHOD No 17

Polyester and certain other fibres

(Method using trichloroacetic acid and chloroform)

1. FIELD OF APPLICATION

This method is applicable, after removal of non-fibrous matter, to binary fibre mixtures of:

1. polyester (35)

with

2. polyacrylate (50)

2. GENERAL INFORMATION

The principle, apparatus and reagent, test procedure, calculation and expression of results that apply to binary fibre mixtures of polyester with polyacrylate are those described in standard EN ISO 1833-25:2013. The 'd' value is 1,01.';

(5) in Annex IX, the following entry 50 is added:

'50.	Polyacrylate	30,00'.

COMMISSION IMPLEMENTING REGULATION (EU) 2018/123

of 15 January 2018

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Cerezas de la Montaña de Alicante' (PGI))

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 Spain's application for the approval of amendments to the specification for the protected geographical indication 'Cerezas de la Montaña de Alicante', registered under Commission Regulation (EC) No 1107/96 ([2]), as amended by Commission Regulation (EU) No 106/2011 ([3]).

(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* ([4]) 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 'Cerezas de la Montaña de Alicante' (PGI) 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*.

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

Done at Brussels, 15 January 2018.

For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) Commission Regulation (EC) No 1107/96 of 12 June 1996 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Council Regulation (EEC) No 2081/92 (OJ L 148, 21.6.1996, p. 1).
([3]) Commission Regulation (EU) No 106/2011 of 7 February 2011 approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications [Cerezas de la Montaña de Alicante (PGI)] (OJ L 32, 8.2.2011, p. 3).
([4]) OJ C 329, 30.9.2017, p. 16.

COMMISSION IMPLEMENTING REGULATION (EU) 2018/124

of 15 January 2018

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ('Pane di Matera' (PGI))

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 geographical indication 'Pane di Matera', registered under Commission Regulation (EC) No 160/2008 ([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 'Pane di Matera' (PGI) 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*.

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

Done at Brussels, 15 January 2018.

For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) Commission Regulation (EC) No 160/2008 of 21 February 2008 registering certain names in the Register of protected designations of origin and protected geographical indications (Pane di Matera (PGI), Tinca Gobba Dorata del Pianalto di Poirino (PDO)) (OJ L 48, 22.2.2008, p. 27).
([3]) OJ C 305, 15.9.2017, p. 20.

COMMISSION IMPLEMENTING REGULATION (EU) 2018/125

of 24 January 2018

amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff [1], and in particular Article 9(1)(e) thereof,

Whereas:

(1) Regulation (EEC) No 2658/87 established a nomenclature of goods (hereinafter referred to as the 'Combined Nomenclature') which is set out in Annex I to that Regulation.

(2) Additional note 2(f) to Chapter 27 of the Combined Nomenclature defines the family of products referred to as 'fuel oils'. These products are classified either in subheadings 2710 19 51 to 2710 19 68 or in subheadings 2710 20 31 to 2710 20 39, depending on their physico-chemical properties and characteristics.

(3) One such physico-chemical characteristic is the saponification number. 'Fuel oils' of additional note 2(f), first paragraph, first indent shall have a saponification number of less than 4. This rule applies to products in subheadings 2710 19 51 to 2710 19 68. However, an exception is made for products in subheadings 2710 20 31 to 2710 20 39 (products containing fatty acid mono-alkyl esters or 'FAMAE') where the saponification number exceeds 4. That exception is currently set out in a footnote to additional note 2(f).

(4) The exception currently in a footnote to additional note 2(f) needs to be extended to take account of developments in technology, in particular the development of renewable fuels containing animal or vegetable fats or oils. It also needs to be extended to tackle the potential for the counterfeiting of diesel fuels that is generally achieved by adding small quantities of vegetable or animal fats or oils to gas oils in order to change their classification from gas oils (which are subject to excise duties) to other products (which are not subject to excise duties). In particular, the addition of vegetable oils serves to change the distillation parameter and to obtain a saponification number equal to or exceeding 4. The addition of small quantities of such substances does not change their essential character as fuel oils from a physico-chemical point of view. They are still used as fuel oils. Removing the requirement in these cases for the saponification number to be less than 4 will therefore ensure that such products are classified correctly as fuel oils, not as other products.

(5) The current exception for products containing FAMAE also needs to be extended so that it covers products where the saponification number equals 4, not just products where it exceeds 4.

(6) Additional note 2(f) to Chapter 27 should be amended accordingly to ensure its uniform interpretation throughout the Union.

(7) Regulation (EEC) No 2658/87 should therefore be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

In Chapter 27 of the Combined Nomenclature set out in Annex I to Regulation (EEC) No 2658/87, additional note 2(f) is amended as follows:

(1) in the first paragraph, the first indent, including the footnote, is replaced by the following:

'— not exceeding that shown in line I of the following table when the sulphated ashes content is less than 1 % by the ISO 3987 method and the saponification number is less than 4 by the ISO 6293-1 or 6293-2 method (except where the product contains one or more bio-components, in which case the requirement in this indent for the saponification number to be less than 4 does not apply),';

[1] OJ L 256, 7.9.1987, p. 1.

(2) the following fourth paragraph is inserted:

'The term "bio-components" means animal or vegetable fats, animal or vegetable oils, or mono-alkyl esters of fatty acids (FAMAE).'.

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, 24 January 2018.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/126

of 24 January 2018

amending Council Regulation (EU) 2016/44 concerning restrictive measures in view of the situation in Libya

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision (CFSP) 2015/1333 of 31 July 2015 concerning restrictive measures in view of the situation in Libya, and repealing Decision 2011/137/CFSP ([1]),

Having regard to Council Regulation (EU) 2016/44 of 18 January 2016 concerning restrictive measures in view of the situation in Libya and repealing Regulation (EU) No 204/2011 ([2]), and in particular Article 20(b) thereof,

Whereas:

(1) Annex V to Regulation (EU) 2016/44 lists vessels designated by the United Nations Sanctions Committee in accordance with paragraph 11 of United Nations Security Council Resolution (UNSCR) 2146 (2014). Those vessels are subject to a number of prohibitions under that Regulation, including the prohibition to load, transport or discharge crude oil from Libya and to access ports in the territory of the Union.

(2) On 18 January 2018, the United Nations Security Council Committee amended the identifying data of vessel 'Capricorn' subject to restrictive measures. Therefore, Annex V to Regulation (EU) 2016/44 should be amended accordingly.

(3) In order to ensure that the measures provided for in this Regulation are effective, this Regulation should enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

Annex V to Council Regulation (EU) 2016/44 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 24 January 2018.

For the Commission,
On behalf of the President,
Head of the Service for Foreign Policy Instruments

([1]) OJ L 206, 1.8.2015, p. 34.
([2]) OJ L 12, 19.1.2016, p. 1.

ANNEX

Annex V to Council Regulation (EU) 2016/44 is amended as follows:

The entry:

'1. **Name:** CAPRICORN

Listed pursuant to paragraphs 10(a) and 10(b) of resolution 2146 (2014), as extended and modified by paragraph 2 of resolution 2362 (2017) (prohibition to load, transport or discharge; prohibition to enter ports). Pursuant to paragraph 11 of resolution 2146, this designation was renewed by the Committee on 20 October 2017 and is valid until 18 January 2018, unless terminated earlier by the Committee pursuant to paragraph 12 of resolution 2146. Flag State: unknown.

Additional information

Listed on 21 July 2017. IMO: 8900878. As of 21 September 2017, the vessel was located in international waters off the United Arab Emirates.'

is replaced by the following:

'1. **Name:** CAPRICORN

Listed pursuant to paragraphs 10(a) and 10(b) of resolution 2146 (2014), as extended and modified by paragraph 2 of resolution 2362 (2017) (prohibition to load, transport or discharge; prohibition to enter ports). Pursuant to paragraph 11 of resolution 2146, this designation was renewed by the Committee on 18 January 2018 and is valid until 17 April 2018, unless terminated earlier by the Committee pursuant to paragraph 12 of resolution 2146. Flag State: unknown.

Additional information

Listed on 21 July 2017. IMO: 8900878. As of 21 September 2017, the vessel was located in international waters off the United Arab Emirates.'

COMMISSION IMPLEMENTING REGULATION (EU) 2018/127

of 24 January 2018

amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 183(b) thereof,

Having regard to Regulation (EU) No 510/2014 of the European Parliament and of the Council of 16 April 2014 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products and repealing Council Regulations (EC) No 1216/2009 and (EC) No 614/2009 ([2]), and in particular Article 5(6)(a) thereof,

Whereas:

(1) Commission Regulation (EC) No 1484/95 ([3]) lays down detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.

(2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin.

(3) Regulation (EC) No 1484/95 should therefore be amended accordingly.

(4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 24 January 2018.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General
Directorate-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 150, 20.5.2014, p. 1.
([3]) Commission Regulation (EC) No 1484/95 of 28 June 1995 laying down detailed rules for implementing the system of additional import duties and fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and repealing Regulation No 163/67/EEC (OJ L 145, 29.6.1995, p. 47).

ANNEX

'ANNEX I

CN code	Description	Representative price (EUR/100 kg)	Security under Article 3 (EUR/100 kg)	Origin [1]
0207 12 10	Fowls of the species *Gallus domesticus*, not cut in pieces, presented as "70 % chickens", frozen	113,6	0	AR
0207 12 90	Fowls of the species *Gallus domesticus*, not cut in pieces, presented as "65 % chickens", frozen	132,5 217,2	0 0	AR BR
0207 14 10	Fowls of the species *Gallus domesticus*, boneless cuts, frozen	250,0 225,3 309,7 253,3	15 22 0 14	AR BR CL TH
0207 27 10	Turkeys, boneless cuts, frozen	336,9 306,0	0 0	BR CL
0408 91 80	Eggs, not in shell, dried	320,6	0	AR
1602 32 11	Preparations of fowls of the species *Gallus domesticus*, uncooked	200,4	26	BR

[1] Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7).'

COMMISSION IMPLEMENTING REGULATION (EU) 2018/128

of 25 January 2018

correcting certain language versions of Implementing Regulation (EU) 2015/504 implementing Regulation (EU) No 167/2013 of the European Parliament and of the Council with regard to the administrative requirements for the approval and market surveillance of agricultural and forestry vehicles

(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 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles ([1]), and in particular Article 34(3) thereof,

Whereas:

(1) An error appears in the Croatian, Estonian, Finnish, Greek, Italian, Latvian, Lithuanian, Maltese, Portuguese, Romanian, Slovenian, Spanish and Swedish language versions of Commission Implementing Regulation (EU) 2015/504 ([2]), where the term 'STAGE 3' in point 4.2.1.3 of Annex IV thereto should appear in English.

(2) In addition, another error appears in the Croatian, Estonian, Greek, Latvian, Lithuanian, Portuguese and Romanian language versions of Implementing Regulation (EU) 2015/504, where the term 'C2a STAGE 1' in the models set out in points 3 and 4 of Appendix 1 of Annex IV thereto should appear in English.

(3) Additional errors appear in the Estonian language version of Implementing Regulation (EU) 2015/504, more precisely in points 2.1.1.6 to 2.1.1.9 and points 4.2.1.6 to 4.2.1.9 of Annex IV thereto, as well as in points 1 to 6 of Appendix 1 to that Annex, in certain letters concerning the model for the statutory plate.

(4) Additional errors appear in the Spanish language version of Implementing Regulation (EU) 2015/504, more precisely in points 2.1.1.6, 2.1.1.7, 2.1.1.9, 4.2.1.6, 4.2.1.7 and 4.2.1.9 of Annex IV thereto, in certain letters concerning the model for the statutory plate.

(5) The Croatian, Estonian, Finnish, Greek, Italian, Latvian, Lithuanian, Maltese, Portuguese, Romanian, Slovenian, Spanish and Swedish language versions of Implementing Regulation (EU) 2015/504 should therefore be corrected accordingly. The other language versions are not concerned by these corrections.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 69(1) of Regulation (EU) No 167/2013,

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 60, 2.3.2013, p. 1.

([2]) Commission Implementing Regulation (EU) 2015/504 of 11 March 2015 implementing Regulation (EU) No 167/2013 of the European Parliament and of the Council with regard to the administrative requirements for the approval and market surveillance of agricultural and forestry vehicles (OJ L 85, 28.3.2015, p. 1).

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

Done at Brussels, 25 January 2018.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/129

of 25 January 2018

concerning the authorisation of L-arginine produced by *Corynebacterium glutamicum* KCCM 80099 as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition 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 L-arginine produced by *Corynebacterium glutamicum* KCCM 80099 as a feed additive for use in feed and in water for drinking. 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 L-arginine produced by *Corynebacterium glutamicum* KCCM 80099 as a feed additive for all animal species to be classified in the additive category 'nutritional additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 May 2017 ([2]) that, under the proposed conditions of use, L-arginine produced by *Corynebacterium glutamicum* KCCM 80099 does not have an adverse effect on animal health, consumer health or the environment and that no safety concerns for users would arise provided that appropriate protective measures are taken.

(5) The Authority also concluded that the additive is an effective source of the amino acid arginine for all animal species and that for the supplemental L-arginine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. The Authority expressed in its opinions a concern over the safety of L-arginine when administered via water for drinking. However, no maximum content for L-arginine is proposed by the Authority. Moreover, the Authority recommends supplementation with L-arginine in appropriate amounts. Thus, it is in the case of supplementation with L-arginine, particularly via drinking water appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids.

(6) 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.

(7) The assessment of L-arginine produced by *Corynebacterium glutamicum* KCCM 80099 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 as specified in the Annex to this Regulation.

(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 substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', 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* 2017; 15(6):4858.

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, 25 January 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/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c362	—	L-arginine	*Additive composition* Powder with a minimum content of L-arginine of 98 % (on a dry matter basis) and a maximum content of 0,5 % water *Characterisation of the active substance* L-arginine ((S)-2-amino-5-guanidinopentanoic acid) produced by fermentation with *Corynebacterium glutamicum* KCCM 80099. Chemical formula: $C_6H_{14}N_4O_2$ CAS number: 74-79-3 *Analytical method* (1) For the characterisation of L-arginine in the feed additive: — Food Chemical Codex 'L-arginine monograph'. For the quantification of arginine in the feed additive and water: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS).	All animal species				1. L-arginine may be placed on the market and used as an additive consisting of a preparation. 2. The additive can be also used via water for drinking. 3. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment and the stability in water for drinking shall be indicated. 4. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-arginine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	15 February 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/kg of complete feed with a moisture content of 12 %			
			For the quantification of arginine in premixtures, feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) — Commission 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 resulting from its use, in particular considering that it is corrosive to skin and eyes. 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 safety glasses and gloves.	

(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) 2018/130

of 25 January 2018

concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) as a feed additive for pigs for fattening (holder of authorisation Berg and Schmidt GmbH Co. KG)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) as a feed additive for pigs for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 25 January 2017 ([2]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) does not have an adverse effect on animal health, human health or the environment. The Authority concluded that the additive is considered efficacious in improving final body weight and feed to gain ration in pigs for fattening. 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 endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) 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 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2017;15(2):4707.

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

Done at Brussels, 25 January 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
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a26	Berg and Schmidt GmbH Co. KG	Endo-1,4-beta-xylanase EC 3.2.1.8	*Additive composition* Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) with a minimum activity of 15 000 EPU (1)/g (solid form) *Characterisation of the active substance* endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) *Analytical method* (2) For quantification of endo-1,4-beta-xylanase activity: colorimetric method measuring water soluble dye released by action of endo-1,4-β-xylanase from azurine cross-linked wheat arabinoxylan substrates.	Pigs for fattening	—	1 500 EPU		1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eyes and breathing protection.	15 February 2028

(1) 1 EPU is the amount of enzyme which releases 0,0083 µmol of reducing sugars (xylose equivalent) per minute from oat spelt xylan at pH 4,7 and 50 °C.
(2) 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.

DIRECTIVES

COUNCIL DIRECTIVE (EU) 2018/131

of 23 January 2018

implementing the Agreement concluded by the European Community Shipowners' Associations (ECSA) and the European Transport Workers' Federation (ETF) to amend Directive 2009/13/EC in accordance with the amendments of 2014 to the Maritime Labour Convention, 2006, as approved by the International Labour Conference on 11 June 2014

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 155(2), in conjunction with points (a), (b) and (c) of Article 153(1), thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) In accordance with Article 155(2) of the Treaty on the Functioning of the European Union (TFEU), management and labour ('the social partners') are able to jointly request that agreements they conclude at Union level be implemented by a Council decision, on a proposal from the Commission.

(2) Council Directive 2009/13/EC ([1]) implemented the agreement concluded on 19 May 2008 by the European Community Shipowners' Associations (ECSA) and the European Transport Workers' Federation (ETF) to incorporate the mandatory provisions of the Maritime Labour Convention, 2006 ('the MLC') of the International Labour Organization (ILO) into Union law, in order to update the Union legislation in force with those standards of the MLC which were more favourable for seafarers. It aimed at improving working conditions for seafarers, particularly as regards employment agreements, working hours, repatriation, careers and skill development, accommodation and recreation facilities, food and catering, health and safety protection, medical care and complaint procedures.

(3) Following international expert meetings, the ILO launched a process to amend the MLC in order to address concerns relating, on the one hand, to the abandonment of seafarers and financial security and, on the other, to claims related to death or long-term disability of seafarers. The Special Tripartite Committee established under the MLC adopted two amendments on those issues at its meeting from 7 to 11 April 2014. Parts of the rules subject to the amendments fell within the Union's competence and concerned matters on which the Union had adopted rules, in particular in social policy and transport. On 26 May 2014 the Council therefore adopted Decision 2014/346/EU ([2]), setting out the position to be adopted on behalf of the Union at the 103rd session of the International Labour Conference (ILC). The position of the Union was to support the approval of the amendments to the MLC Code ('the 2014 amendments to the MLC').

(4) The 2014 amendments to the MLC were approved by the ILC at its 103rd session in Geneva on 11 June 2014 and entered into force on 18 January 2017. They relate to providing an effective financial security system to protect seafarers' rights in the event of abandonment and to assure compensation for contractual claims for death or long-term disability of seafarers due to occupational injury, illness or hazard. They improve and optimise the existing system for protecting seafarers, including the obligation for ships to carry documentary evidence on board of the financial security system and to extend the system to cover two new situations of abandonment.

([1]) Council Directive 2009/13/EC of 16 February 2009 implementing the Agreement concluded by the European Community Shipowners' Associations (ECSA) and the European Transport Workers' Federation (ETF) on the Maritime Labour Convention, 2006, and amending Directive 1999/63/EC (OJ L 124, 20.5.2009, p. 30).

([2]) Council Decision 2014/346/EU of 26 May 2014 on the position to be adopted on behalf of the European Union at the 103rd session of the International Labour Conference concerning amendments to the Code of the Maritime Labour Convention (OJ L 172, 12.6.2014, p. 28).

Those situations relate to cases in which seafarers have been left without the necessary maintenance and support or to cases in which the shipowner has unilaterally severed its ties with the seafarer, including failure to pay contractual wages for a period of at least 2 months.

(5) On 5 December 2016 the social partners in the maritime transport sector — the ECSA and the ETF — concluded an agreement ('the social partners' agreement') to amend Directive 2009/13/EC in accordance with the 2014 amendments to the MLC. On 12 December 2016 they requested that the Commission present a proposal for a Council directive under Article 155(2) of the TFEU in order to implement that agreement.

(6) The social partners' agreement reproduces the content of the mandatory provisions of the 2014 amendments to the MLC. The first amendment, on the financial security system in the event of abandonment of the seafarer, relates both to health and safety and to working conditions, and is thus covered by points (a) and (b) of Article 153(1) of the TFEU. The second amendment, on the requirements of the financial security system to assure compensation in the event of the death or long-term disability of seafarers due to an occupational injury, illness or hazard, is covered by point (c) of Article 153(1) of the TFEU, on social security and social protection of workers. The social partners' agreement therefore relates to matters covered by Article 153 of the TFEU and can be implemented by a Council decision on a proposal from the Commission, in accordance with Article 155(2) of the TFEU. For the purposes of Article 288 of the TFEU, the appropriate instrument to implement the social partners' agreement is a directive.

(7) In accordance with the Commission communication of 20 May 1998 on adapting and promoting the social dialogue at Community level, the Commission has assessed the representative status of the signatory parties and the legality of each clause of the social partners' agreement.

(8) The social partners' agreement amends the agreement concluded on 19 May 2008 between ECSA and the ETF on the MLC, annexed to Directive 2009/13/EC, and incorporates into that Directive the 2014 amendments to the MLC in order to improve the working conditions, health and safety and social protection for seafarers on board ships flying the flag of a Member State.

(9) In amending Directive 2009/13/EC, the social partners' agreement will bring the mandatory provisions of the 2014 amendments to the MLC, which are already covered by the MLC supervisory system, within the scope of Directive 2013/54/EU of the European Parliament and of the Council ([1]) and of the Union law supervisory and monitoring system, including the jurisdiction of the Court of Justice of the European Union. This is likely to result in greater compliance by Member States and shipowners.

(10) Without prejudice to the provisions of the social partners' agreement on follow-up and review by the social partners at Union level, the Commission will monitor the implementation of this Directive and of the social partners' agreement.

(11) The Member States are able to entrust social partners with the implementation of this Directive where the latter jointly request this and provided that the Member States take all necessary steps to ensure that they can at all times guarantee the results sought under this Directive.

(12) Pursuant to Article 155(2) of the TFEU, the Commission has informed the European Parliament by sending it the text of its proposal for this Directive.

(13) This Directive respects the fundamental rights and observes the principles recognised in the Charter of Fundamental Rights of the European Union, and in particular Article 31 thereof.

(14) Since the objectives of this Directive, namely to improve the working conditions, health and safety and social protection of workers in the maritime transport sector, which is a cross-border sector operating under the flags of different Member States, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.

([1]) Directive 2013/54/EU of the European Parliament and of the Council of 20 November 2013 concerning certain flag State responsibilities for compliance with and enforcement of the Maritime Labour Convention, 2006 (OJ L 329, 10.12.2013, p. 1).

(15) Directive 2009/13/EC should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive implements the agreement concluded between the European Community Shipowners' Associations (ECSA) and the European Transport Workers' Federation (ETF) on 5 December 2016 to amend Directive 2009/13/EC in accordance with the 2014 amendments to the MLC.

Article 2

In line with the social partners' agreement, the Agreement concluded by the ECSA and the ETF on the Maritime Labour Convention, 2006, set out in the Annex to Directive 2009/13/EC is amended in accordance with the Annex to this Directive.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 16 February 2020. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.

3. Member States may entrust social partners with the implementation of this Directive where social partners jointly request to do so and provided that the Member States take all the necessary steps to ensure that they can at all times guarantee the results sought under this Directive.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 23 January 2018.

For the Council
The President
V. GORANOV

ANNEX

In the Annex to Directive 2009/13/EC, the Agreement concluded by the ECSA and the ETF on the Maritime Labour Convention, 2006, is amended as follows:

(1) in the heading 'Standard A2.5 — Repatriation', 'A2.5' is replaced by 'A2.5.1'.

(2) the following Standard is inserted:

'Standard A2.5.2 — Financial security

1. In implementation of Regulation 2.5, paragraph 2, this Standard establishes requirements to ensure the provision of an expeditious and effective financial security system to assist seafarers in the event of their abandonment.

2. For the purposes of this Standard, a seafarer shall be deemed to have been abandoned where, in violation of the requirements of this Agreement or the terms of the seafarers' employment agreement, the shipowner:

   (a) fails to cover the cost of the seafarer's repatriation; or

   (b) has left the seafarer without the necessary maintenance and support; or

   (c) has otherwise unilaterally severed their ties with the seafarer including failure to pay contractual wages for a period of at least 2 months.

3. Each Member State shall ensure that a financial security system meeting the requirements of this Standard is in place for ships flying its flag. The financial security system may be in the form of a social security scheme or insurance or a national fund or other similar arrangements. Its form shall be determined by the Member State after consultation with the shipowners' and seafarers' organisations concerned.

4. The financial security system shall provide direct access, sufficient coverage and expedited financial assistance, in accordance with this Standard, to any abandoned seafarer on a ship flying the flag of the Member State.

5. For the purposes of paragraph 2(b) of this Standard, necessary maintenance and support of seafarers shall include: adequate food, accommodation, drinking water supplies, essential fuel for survival on board the ship and necessary medical care.

6. Each Member State shall require that ships that fly its flag, and which are required under national laws to carry a Maritime Labour Certificate or do so at the request of the shipowner, carry on board a certificate or other documentary evidence of financial security issued by the financial security provider. A copy shall be posted in a conspicuous place on board where it is available to the seafarers. Where more than one financial security provider provides cover, the document provided by each provider shall be carried on board.

7. The certificate or other documentary evidence of financial security shall be in English or accompanied by an English translation and contain the following information:

   (a) name of the ship;

   (b) port of registry of the ship;

   (c) call sign of the ship;

   (d) IMO number of the ship;

   (e) name and address of the provider or providers of the financial security;

   (f) contact details of the persons or entity responsible for handling seafarers' requests for relief;

   (g) name of the shipowner;

   (h) period of validity of the financial security; and

   (i) an attestation from the financial security provider that the financial security meets the requirements of this Standard A2.5.2.

8. Assistance provided by the financial security system shall be granted promptly upon request made by the seafarer or the seafarer's nominated representative and supported by the necessary justification of entitlement in accordance with paragraph 2 of this Standard.

9. Having regard to Regulation 2.5, assistance provided by the financial security system shall be sufficient to cover the following:

   (a) outstanding wages and other entitlements due from the shipowner to the seafarer under their employment agreement, the relevant collective bargaining agreement or the national law of the flag State, limited to 4 months of any such outstanding wages and 4 months of any such outstanding entitlements;

   (b) all expenses reasonably incurred by the seafarer, including the cost of repatriation referred to in paragraph 10 of this Standard; and

   (c) the essential needs of the seafarer including such items as: adequate food, clothing where necessary, accommodation, drinking water supplies, essential fuel for survival on board the ship, necessary medical care and any other reasonable costs or charges from the act or omission constituting the abandonment until the seafarer's arrival at home.

10. The cost of repatriation shall cover travel by appropriate and expeditious means, normally by air, and include provision for food and accommodation of the seafarer from the time of leaving the ship until arrival at the seafarer's home, necessary medical care, passage and transport of personal effects and any other reasonable costs or charges arising from the abandonment.

11. The financial security shall not cease before the end of the period of validity of the financial security unless the financial security provider has given prior notification of at least 30 days to the competent authority of the flag State.

12. If the provider of insurance or other financial security has made any payment to any seafarer in accordance with this Standard, such provider shall, up to the amount it has paid and in accordance with the applicable law, acquire by subrogation, assignment or otherwise, the rights which the seafarer would have enjoyed.

13. Nothing in this Standard shall prejudice any right of recourse of the insurer or provider of financial security against third parties.

14. The provisions in this Standard are not intended to be exclusive or to prejudice any other rights, claims or remedies that may also be available to compensate seafarers who are abandoned. National laws and regulations may provide that any amounts payable under this Standard can be offset against amounts received from other sources arising from any rights, claims or remedies that may be the subject of compensation under the present Standard.'.

(3) 'Standard A4.2 — Shipowners' liability' is amended as follows:

(a) in the heading, 'A4.2' is replaced by 'A4.2.1';

(b) the following paragraphs are added:

'8. National laws and regulations shall provide that the system of financial security to assure compensation as provided by paragraph 1(b) of this Standard for contractual claims, as defined in Standard A4.2.2, meet the following minimum requirements:

   (a) the contractual compensation, where set out in the seafarer's employment agreement and without prejudice to subparagraph (c) of this paragraph, shall be paid in full and without delay;

   (b) there shall be no pressure to accept a payment less than the contractual amount;

   (c) where the nature of the long-term disability of a seafarer makes it difficult to assess the full compensation to which the seafarer may be entitled, an interim payment or payments shall be made to the seafarer so as to avoid undue hardship;

   (d) in accordance with Regulation 4.2, paragraph 2, the seafarer shall receive payment without prejudice to other legal rights, but such payment may be offset by the shipowner against any damages resulting from any other claim made by the seafarer against the shipowner and arising from the same incident; and

   (e) the claim for contractual compensation may be brought directly by the seafarer concerned, or their next of kin, or a representative of the seafarer or designated beneficiary.

9. National laws and regulations shall ensure that seafarers receive prior notification if a shipowner's financial security is to be cancelled or terminated.

10. National laws and regulations shall ensure that the competent authority of the flag State is notified by the provider of the financial security if a shipowner's financial security is cancelled or terminated.

11. Each Member State shall require that ships that fly its flag carry on board a certificate or other documentary evidence of financial security issued by the financial security provider. A copy shall be posted in a conspicuous place on board where it is available to the seafarers. Where more than one financial security provider provides cover, the document provided by each provider shall be carried on board.

12. The financial security shall not cease before the end of the period of validity of the financial security unless the financial security provider has given prior notification of at least 30 days to the competent authority of the flag State.

13. The financial security shall provide for the payment of all contractual claims covered by it which arise during the period for which the document is valid.

14. The certificate or other documentary evidence of financial security shall be in English or accompanied by an English translation and contain the following information:

(a) name of the ship;

(b) port of registry of the ship;

(c) call sign of the ship;

(d) IMO number of the ship;

(e) name and address of the provider or providers of the financial security;

(f) contact details of the persons or entity responsible for handling seafarers' contractual claims;

(g) name of the shipowner;

(h) period of validity of the financial security; and

(i) an attestation from the financial security provider that the financial security meets the requirements of Standard A4.2.1.'.

(4) the following standard is inserted:

'Standard A4.2.2 — Treatment of contractual claims

1. For the purposes of Standard A4.2.1, paragraph 8, and the present Standard, the term "contractual claim" means any claim which relates to death or long-term disability of seafarers due to an occupational injury, illness or hazard as set out in national law, the seafarers' employment agreement or collective agreement.

2. The system of financial security, as provided for in Standard A4.2.1, paragraph 1(b), may be in the form of a social security scheme or insurance or fund or other similar arrangements. Its form shall be determined by the Member State after consultation with the shipowners' and seafarers' organisations concerned.

3. National laws and regulations shall ensure that effective arrangements are in place to receive, deal with and impartially settle contractual claims relating to compensation referred to in Standard A4.2.1, paragraph 8, through expeditious and fair procedures.'.

DECISIONS

COUNCIL IMPLEMENTING DECISION (CFSP) 2018/132

of 25 January 2018

implementing Decision (CFSP) 2015/1333 concerning restrictive measures in view of the situation in Libya

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Decision (CFSP) 2015/1333 of 31 July 2015 concerning restrictive measures in view of the situation in Libya, and repealing Decision 2011/137/CFSP [1], and in particular Article 12(1) thereof,

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

Whereas:

(1) On 31 July 2015, the Council adopted Decision (CFSP) 2015/1333.

(2) On 18 January 2018, the United Nations Security Council Committee established pursuant to United Nations Security Council Resolution 1970 (2011) renewed and amended the listing of a vessel subject to restrictive measures.

(3) Annex V to Decision (CFSP) 2015/1333 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex V to Decision (CFSP) 2015/1333 is hereby amended as set out in the Annex to this Decision.

Article 2

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

Done at Brussels, 25 January 2018.

For the Council
The President
E. KRALEVA

[1] OJ L 206, 1.8.2015, p. 34.

ANNEX

In section B (Entities) of Annex V to Decision (CFSP) 2015/1333, entry 1 is replaced by the following:

'1. **Name:** CAPRICORN

A.k.a.: na **F.k.a.:** na **Address:** na **Listed on:** 21 July 2017 (amended on 20 October 2017, 27 November 2017, and 18 January 2018)

Additional information

IMO: 8900878. Listed pursuant to paragraphs 10 (a) and 10 (b) of Resolution 2146 (2014), as extended and modified by paragraph 2 of Resolution 2362 (2017) (prohibition to load, transport or discharge; prohibition to enter ports). Pursuant to paragraph 11 of Resolution 2146, this designation was renewed by the Committee on 18 January 2018 and is valid until 17 April 2018, unless terminated earlier by the Committee pursuant to paragraph 12 of Resolution 2146. Flag State: unknown. As of 21 September 2017, the vessel was located in international waters off the United Arab Emirates.'.

COMMISSION IMPLEMENTING DECISION (EU) 2018/133

of 24 January 2018

amending Decision 2008/911/EC shing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

(notified under document C(2018) 213)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ([1]), and in particular Article 16f thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 2 February 2016 by the Committee for Herbal Medicinal Products,

Whereas:

(1) *Valeriana officinalis* L. can be considered as a herbal substance, a herbal preparation or a combination thereof within the meaning of Directive 2001/83/EC and it complies with the requirements set out in that Directive.

(2) It is therefore appropriate to include *Valeriana officinalis* L. in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established by Commission Decision 2008/911/EC ([2]).

(3) Decision 2008/911/EC should therefore be amended accordingly.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Annexes I and II to Decision 2008/911/EC are amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 24 January 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

([1]) OJ L 311, 28.11.2001, p. 67.
([2]) Commission Decision 2008/911/EC of 21 November 2008 establishing of a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (OJ L 328, 6.12.2008, p. 42).

ANNEX

Decision 2008/911/EC is amended as follows:

(1) in Annex I, the following substance is inserted after *Thymus vulgaris* L., *Thymus zygis* Loefl. ex L., aetheroleum:

'*Valeriana officinalis* L.';

(2) in Annex II, the following is inserted after the COMMUNITY LIST ENTRY on *Thymus vulgaris* L., *Thymus zygis* Loefl. ex L., aetheroleum:

'UNION LIST ENTRY ON *VALERIANA OFFICINALIS* L.

Scientific name of the plant

Valeriana officinalis L.

Botanical family

Valerianaceae

Common name in all EU official languages of herbal preparation

BG (bălgarski): Валериана, корен
CS (čeština): kozlíkový kořen
DA (dansk): Baldrianrod
DE (Deutsch): Baldrianwurzel
EL (elliniká): Ρίζα βαλεριανής
EN (English): Valerian root
ES (español): Valeriana, raíz de
ET (eesti keel): palderjanijuur
FI (suomi): rohtovirmajuuri, juuri
FR (français): Valériane (racine de)
HR (hrvatska): odoljenov korijen
HU (magyar): Macskagyökér
IT (italiano): Valeriana radice
LT (lietuvių kalba): Valerijonų šaknys
LV (latviešu valoda): Baldriāna saknes
MT (Malti): Għerq tal-Valerjana
NL (Nederlands): Valeriaanwortel
PL (polski): Korzeń kozłka
PT (português): Valeriana, raiz
RO (română): rădăcină de valeriană
SK (slovenčina): Koreň valeriány
SL (slovenščina): korenina zdravilne špajke
SV (svenska): Vänderot, rot
IS (íslenska):
NO (norsk): Valerianarot

Herbal preparation(s)

(a) Comminuted herbal substance
(b) Powdered herbal substance
(c) Expressed juice from fresh root (1:0,60-0,85)
(d) Dry extract (DER 4-6:1), extraction solvent: water
(e) Liquid extract (DER 1:4-6), extraction solvent: water
(f) Dry extract (DER 4-7:1), extraction solvent: methanol 45 % (V/V)
(g) Dry extract (DER 5,3-6,6:1), extraction solvent: methanol 45 % (m/m)
(h) Liquid extract (DER 1:7-9), extraction solvent: sweet wine
(i) Liquid extract (DER 1:1), extraction solvent: ethanol 60 % (V/V)
(j) Tincture (ratio of herbal substance to extraction solvent 1:8), extraction solvent: ethanol 60 % (V/V)
(k) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent: ethanol 56 %
(l) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 70 % (V/V)
(m) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 60-80 % (V/V)
(n) Dry extract (DER 5,5-7,4:1), extraction solvent: ethanol 85 % (m/m)

European Pharmacopoeia monograph reference

04:2017:0453

Indications

Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep.

The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

Type of tradition

European.

Specified strength

Please see 'Specified posology'.

Specified posology

Adolescents, adults and elderly

Oral use

(a) single dose: 0,3-3 g

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

Herbal tea: 0,3-3 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion

(b) single dose: 0,3-2,0 g

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

(c) single dose: 10 ml

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

(d) single dose: 420 mg

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

(e) single dose: 20 ml

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime.

(f) single dose: 144-288 mg

For relief of mild symptoms of mental stress up to 4 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

(g) single dose: 450 mg

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half to one hour before bedtime with an earlier dose during the evening if necessary.

(h) single dose: 10 ml, up to 3 times daily

(i) single dose: 0,3-1,0 ml, up to 3 times daily

(j) single dose: 4-8 ml, up to 3 times daily

(k) single dose: 0,84 ml

For relief of mild symptoms of mental stress 3-5 times daily.

To aid sleep, a single dose half an hour before bedtime.

(l) single dose: 1,5 ml (mental stress), 3 ml (to aid sleep)

For relief of mild symptoms of mental stress up to 3 times daily.

To aid sleep, a single dose half an hour before bedtime.

(m) single dose: 10 ml, up to 3 times daily

(n) single dose: 322 mg, up to 3 times daily

Use as bath additive

single dose: 100 g for a full bath, up to 1 bath daily

Route of administration

Oral use

Use as bath additive. Temperature: 34-37 °C, duration of bath 10-20 minutes.

Duration of use or any restrictions on the duration of use

If symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Any other information necessary for the safe use

Contraindications

Hypersensitivity to the active substance.

Use as bath additive

Full baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac insufficiency.

Special warnings and precautions for use

The use in children under 12 years of age has not been established due to lack of adequate data.

If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

Interactions with other medicinal products and other forms of interaction

None reported

Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, use during pregnancy and lactation is not recommended.

No fertility data available.

Effects on ability to drive and use machines

May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

Undesirable effects

Oral use

Gastrointestinal symptoms (e.g. nausea, abdominal cramps) may occur after ingestion of valerian root preparations. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

Use as bath additive

None known

If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

Overdose

Oral use

Valerian root at a dose of approximately 20 g caused symptoms, such as fatigue, abdominal cramp, chest tightness, light-headedness, hand tremor and mydriasis, which disappeared within 24 hours. If symptoms arise, treatment should be supportive.

Use as bath additive

No case of overdose has been reported.

Pharmaceutical particulars [If necessary]

Not applicable

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary for the safe use of the product]

Not applicable.'

COMMISSION IMPLEMENTING DECISION (EU) 2018/134

of 24 January 2018

amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

(notified under document C(2018) 218)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ([1]), and in particular Article 16f thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 2 February 2016 by the Committee for Herbal Medicinal Products

Whereas:

(1) *Sideritis scardica* Griseb., herba can be considered as a herbal substance, a herbal preparation or a combination thereof within the meaning of Directive 2001/83/EC and it complies with the requirements set out in that Directive.

(2) It is therefore appropriate to include *Sideritis scardica* Griseb., herba in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established by Commission Decision 2008/911/EC ([2]).

(3) Decision 2008/911/EC should therefore be amended accordingly.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Annexes I and II to Decision 2008/911/EC are amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 24 January 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

([1]) OJ L 311, 28.11.2001, p. 67.
([2]) Commission Decision 2008/911/EC of 21 November 2008 establishing of a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (OJ L 328, 6.12.2008, p. 42).

ANNEX

Decision 2008/911/EC is amended as follows:

(1) In Annex I, the following substance is inserted after *Pimpinella anisum* L:

'*Sideritis scardica* Griseb., herba.';

(2) In Annex II, the following is inserted after the COMMUNITY LIST ENTRY on *Pimpinella anisum* L:

'UNION LIST ENTRY ON *SIDERITIS SCARDIA* GRISEB., HERBA

Scientific name of the plant

Sideritis scardica Griseb.

Botanical family

Lamiaceae (Labiatae)

Herbal substance

Ironwort (*Sideritis herba*)

Common name in all EU official languages of herbal preparation

BG (bălgarski): Мурсалски чай, стрък
CS (čeština): nať hojníku
DA (dansk): Kortkroneurt
DE (Deutsch): Balkan-Gliedkraut
EL (elliniká): Πόα σιδηρίτου
EN (English): Ironwort
ES (español): Siderita, partes aéreas de
ET (eesti keel): haavarohuürt
FI (suomi): raudakki, verso
FR (français): Crapaudine (parties aériennes de)
HR (hrvatska): očistova zelen
HU (magyar): sármányvirág virágos hajtása
IT (italiano): Stregonia parti aeree fiorite
LT (lietuvių kalba): Timsrų žolė
LV (latviešu valoda): Siderītu laksts
MT (Malti): ħaxixa tas-Sideritis
NL (Nederlands): (Griekse) bergthee, kruid
PL (polski): Ziele gojnika
PT (português): Siderite, partes aéreas
RO (română): iarba de ceaiul muntelui cretan
SK (slovenčina): Vňať ránhoja
SL (slovenščina): zel sklepnjaka
SV (svenska): Sårmynta, ört
IS (íslenska):
NO (norsk): Gresk fjellte

Herbal preparations

Comminuted herbal substance

European Pharmacopoeia monograph reference

Not applicable

Indications

Indication (1)

Traditional herbal medicinal product used for the relief of cough associated with cold.

Indication (2)

Traditional herbal medicinal product used for the relief of mild gastrointestinal discomfort.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

Type of tradition

European

Specified strength

Please see "Specified posology".

Specified posology

Adults and elderly

Indication (1) and (2)

Single dose: Herbal tea: 2-4 g of the comminuted herbal substance in 150-200 ml of water as a herbal infusion 2-3 times daily
Daily dose: up to 12 g
The use in children and adolescents under 18 years of age is not recommended (see section "Special warnings and precautions for use")

Route of administration

Oral use

Duration of use or any restrictions on the duration of use

Indication (1)

If symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Indication (2)

If symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Any other information necessary for the safe use

Contraindications

Hypersensitivity to the active substance and to other plants of the Lamiaceae (Labiatae) family.

Special warnings and precautions for use

The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.
If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Interactions with other medicinal products and other forms of interaction

None reported

Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, use during pregnancy and lactation is not recommended.
No fertility data available.

Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

Undesirable effects

None known
If adverse reactions occur, a doctor or qualified health care practitioner should be consulted.

Overdose

No case of overdose has been reported.

Pharmaceutical particulars (if necessary)

Not applicable

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience (if necessary for the safe use of the product)

Not applicable.'

CORRIGENDA

Corrigendum to Commission Delegated Regulation (EU) 2018/44 of 20 October 2017 amending Delegated Regulation (EU) 2016/2374 establishing a discard plan for certain demersal fisheries in South-Western waters

(Official Journal of the European Union L 7 of 12 January 2018)

On page 4, in the Annex, Sections 3 and 6, note 1 of the tables and on page 5, Section 7, note 1 of the table:

for: '(1) Reference period for the year 2017. For 2018 the reference period shall be 2015/2016 and for 2019 the reference period shall be 2016/2017.',

read: '(1) Reference period for the year 2017. For 2018 the reference period shall be 2015/2016'.

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