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⁽¹⁾ Text with EEA relevance.

EN

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

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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2023/1141

of 1 June 2023

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health*(Text with EEA relevance)*

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 18(5) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006, health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in the Union list of permitted health claims.
- (2) Regulation (EC) No 1924/2006 also provides that applications for authorisation of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority ('the Authority').
- (3) Following the receipt of an application, the Authority is to inform without delay the other Member States and the Commission, and to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of the health claim taking into account the opinion delivered by the Authority.
- (5) Following an application from Nestlé S.A., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to beta-glucans sourced from oats and/or barley in ready-to-eat breakfast cereals manufactured via pressure cooking and to the reduction of blood glucose rise after consumption (Question No EFSA-Q-2020-000447). The claim proposed by the applicant was worded as follows: 'Consumption of beta-glucans from oats and/or barley in a ready-to-eat breakfast cereal contributes to a reduction of the blood glucose rise after that meal'.
- (6) On 8 April 2021, the Commission and the Member States received the scientific opinion ⁽²⁾ on that claim from the Authority, which concluded that, on the basis of the data presented, the effect of beta-glucans in reducing post-prandial blood glucose responses is well established. However, the evidence provided had been insufficient to establish an effect on reduction of post-prandial glycaemic responses at doses of 1,3 g beta-glucans per 25 g of available carbohydrate incorporated into ready-to-eat breakfast cereals manufactured by pressure cooking (i.e. either

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.⁽²⁾ EFSA Journal 2021;19(4):6493.

batch cooking or extrusion), as requested by the applicant. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted health claims, it should not be authorised.

- (7) Following an application from Pharmactive Biotech Products, S.L., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to Affron® and the contribution to the maintenance of a healthy mood (Question No EFSA-Q-2020-00617). The claim proposed by the applicant was worded as follows: 'Affron® contributes to maintain a healthy mood by reducing the negative traits of depressive and anxiety feelings'.
- (8) On 6 July 2021, the Commission and the Member States received the scientific opinion ⁽³⁾ on that claim from the Authority, which concluded that, on the basis of the data presented, the evidence provided had been insufficient to establish a cause and effect relationship between the consumption of Affron® and increase in positive mood. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted health claims, it should not be authorised.
- (9) Following an application from Praline i Cokolada j.d.o.o., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to MegaNatural®-BP grape seed extract and the maintenance of normal blood pressure (Question No EFSA-Q-2020-00718). The claim proposed by the applicant was worded as follows: 'MegaNatural®-BP helps maintain healthy blood pressure'.
- (10) On 9 August 2021, the Commission and the Member States received the scientific opinion ⁽⁴⁾ on that claim from the Authority, which concluded that, on the basis of the data presented, the evidence provided had been insufficient to establish a cause and effect relationship between the consumption of MegaNatural®-BP, a grape seed extract standardised for total phenolics, gallic acid and the sum of catechin and epicatechin content, and maintenance of normal blood pressure. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted health claims, it should not be authorised.
- (11) Following an application from Sensus B.V. (Royal Cosun), submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on the scientific substantiation of a health claim related to Frutalose® and the maintenance of normal defecation (Question No EFSA-Q-2020-00631). The claim proposed by the applicant was worded as follows: 'Frutalose® chicory oligofructose contributes to regular bowel function by increasing stool frequency'. The applicant also provided three alternative wordings for the claim.
- (12) On 12 August 2021, the Commission and the Member States received the scientific opinion ⁽⁵⁾ on that claim from the Authority, which concluded that, on the basis of the data presented, the evidence provided was insufficient to establish a cause and effect relationship between the consumption of Frutalose® and the maintenance of normal defecation under the proposed conditions of use. Accordingly, as the health claim does not comply with the requirements of Regulation (EC) No 1924/2006 for the inclusion in the Union list of permitted health claims, it should not be authorised.
- (13) The comments by Nestlé S.A. on the Authority's opinion on the health claim relating to beta-glucans sourced from oats and/or barley in ready-to-eat breakfast cereals manufactured via pressure cooking and to the reduction of blood glucose rise after consumption (Question No EFSA-Q-2020-000447), received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006, have been considered when adopting this Regulation.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽³⁾ EFSA Journal 2021;19(7):6669.

⁽⁴⁾ EFSA Journal 2021;19(8):6776.

⁽⁵⁾ EFSA Journal 2021;19(8):6775.

HAS ADOPTED THIS REGULATION:

Article 1

The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted health claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

Article 2

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

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

Done at Brussels, 1 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

Rejected health claims

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Beta-glucans sourced from oats and/or barley, incorporated into ready-to-eat breakfast cereals manufactured via pressure cooking (i.e. either by batch cooking or extrusion), and present at a level of at least 1,3 g per 25 g available carbohydrate in the ready-to-eat cereal	Consumption of beta-glucans from oats and/or barley in a ready-to-eat breakfast cereal contributes to a reduction of the blood glucose rise after that meal	Q-2020-000447
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Affron®, aqueous saffron extract, with the sum of crocins and safranal concentration > 3,5 % and dextrin as inert carrier	Affron® contributes to maintain a healthy mood by reducing the negative traits of depressive and anxiety feelings	Q-2020-00617
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	MegaNatural®-BP grape seed extract made entirely of California-grown grapes containing biologically active constituents: total phenolics (90–93 %), gallic acid (≥ 2 %) and catechin and epicatechin (≥ 5 %). The distribution of phenolic compounds in the MegaNatural®-BP is on average 9 % monomers, 69 % oligomers and 22 % polymers	MegaNatural®-BP helps maintain healthy blood pressure	Q-2020-00718
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Frutalose® chicory oligofructose	Frutalose® chicory oligofructose contributes to regular bowel function by increasing stool frequency (And three other alternative wordings)	Q-2020-00631

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1142**of 9 June 2023****amending Implementing Regulations (EU) 2020/761 and (EU) 2020/1988 as regards the quantities that may be imported under certain tariff quotas following the agreement between the European Union and the United States of America**

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 187 thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2020/761 ⁽²⁾ lays down the rules for the management of import and export tariff quotas for agricultural products managed by a system of import and export licences and provides for specific rules.
- (2) Commission Implementing Regulation (EU) 2020/1988 ⁽³⁾ lays down the rules for the administration of import tariff quotas designed to be used following the chronological order of dates of acceptance of customs declarations ('first come, first served' principle).
- (3) The Agreement between the European Union and the United States of America pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom's withdrawal from the European Union, concluded by Council Decision (EU) 2023/912 ⁽⁴⁾, amends the quantities of products to be imported under some tariff quotas opened in favour of the United States and some tariff quotas opened for all other countries. The tariff quotas with following order numbers are concerned: 09.0035, 09.0040, 09.0041, 09.0055, 09.0056, 09.0059, 09.0070, 09.0073, 09.0083, 09.0089, 09.0093, 09.0094, 09.0123, 09.0147, 09.4002, 09.4038, 09.4116, 09.4123, 09.4127 and 09.4170.
- (4) The amendments made by that Agreement should be reflected in Annexes to Implementing Regulations (EU) 2020/761 and (EU) 2020/1988.
- (5) Implementing Regulations (EU) 2020/761 and (EU) 2020/1988 should therefore be amended accordingly.
- (6) Transitional provisions are needed to clarify how to handle the situations that may arise as a result of the amendments of quantities of products to be imported under the tariff quotas concerned. This concerns tariff quotas that are managed in periods divided into sub-periods. It also concerns tariff quotas that are managed in accordance with the first come, first served principle, where the amendment of quantities leads to either an increase of the quantity of a tariff quota that was exhausted or to a decrease of the available quantity of a tariff quota for products that were already released for free circulation in the Union.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ Commission Implementing Regulation (EU) 2020/761 of 17 December 2019 laying down rules for the application of Regulations (EU) No 1306/2013, (EU) No 1308/2013 and (EU) No 510/2014 of the European Parliament and of the Council as regards the management system of tariff quotas with licences (OJ L 185, 12.6.2020, p. 24).

⁽³⁾ Commission Implementing Regulation (EU) 2020/1988 of 11 November 2020 laying down rules for the application of Regulations (EU) No 1308/2013 and (EU) No 510/2014 of the European Parliament and of the Council as regards the administration of import tariff quotas in accordance with the 'first come, first served' principle (OJ L 422, 14.12.2020, p. 4).

⁽⁴⁾ Council Decision (EU) 2023/912 of 25 April 2023 on the conclusion, on behalf of the Union, of the Agreement between the European Union and the United States of America pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff rate quotas included in the EU schedule CLXXV as a consequence of the United Kingdom's withdrawal from the European Union (OJ L 119, 5.5.2023, p. 1).

- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2020/761

Annexes II, III, VIII, and X are amended in accordance with Annex I to this Regulation.

Article 2

Amendment to Implementing Regulation (EU) 2020/1988

Annex I is amended in accordance with Annex II to this Regulation.

Article 3

Transitional provisions

1. With regard to the amendments introduced by Article 1, where the tariff quota period of a given tariff quota has already started on the day of entry into force of this Regulation, the difference between the new quantity and the quantity already allocated shall be made available:

- (a) from the first application period after the entry into force of this Regulation, if the tariff quota period is not divided into sub-periods;
- (b) according to the specific rules applicable to each tariff quota, if the tariff quota has a period divided in sub-periods.

If one or more sub-periods have already expired at the moment of the entry into force of this Regulation, the difference between the new quantity available in the sub-periods expired before the entry into force of this Regulation and the quantity actually allocated shall be made available as from the first application period after the entry into force of this Regulation.

2. With regard to the amendments introduced by Article 2, the difference between the new quantity and the quantity already released for free circulation before the entry into force of this Regulation shall be made available from the day of entry into force of this Regulation.

In case of an increase of the quantity set out in Annex I to Implementing Regulation (EU) 2020/1988, if on the day of entry into force of this Regulation the relevant tariff quota period has already started and the quantity previously available is exhausted, the difference between the new quantity and the previous quantity shall be allocated to operators following the chronological order of the acceptance date of the customs declaration for release for free circulation. Operators who imported their goods out of quota before the entry into force of this Regulation, and who will benefit of the allocation of the additional quantity, shall be reimbursed the difference between the duty already paid and the in-quota duty.

In case of a decrease of the quantity set out in Annex I to Implementing Regulation (EU) 2020/1988, if on the day of entry into force of this Regulation the relevant tariff quota period has already started and a quantity higher than the new one has already been released for free circulation, operators shall not be required to pay any additional duty for the in-quota quantities imported exceeding the new available volumes.

*Article 4***Entry into force and application**

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

Article 1 shall apply from the first licence application period starting after the entry into force of this Regulation.

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

Done at Brussels, 9 June 2023.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

Annexes I, II, III, VIII, and X to Implementing Regulation (EU) 2020/761 are amended as follows:

- (1) in Annex I, the row relating to the tariff quota with order number 09.4170 is deleted;
- (2) in Annex II, in the table relating to the tariff quota with order number 09.4123, the row 'Quantity in kg' is replaced by the following:

'Quantity in kg'	572 000 000 kg
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- (3) Annex III is amended as follows:

- (a) in the table relating to the tariff quota with order number 09.4116, the row 'Quantity in kg' is replaced by the following:

'Quantity in kg'	1 910 000 kg, divided as follows: 1 910 000 kg for sub-period 1 January to 30 June Carry over from previous sub-periods, for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 31 December
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- (b) in the table relating to the tariff quota with order number 09.4127, the row 'Quantity in kg' is replaced by the following:

'Quantity in kg'	25 772 000 kg, divided as follows: 7 153 000 kg for sub-period 1 January to 31 March 11 466 000 kg for sub-period 1 April to 30 June 7 153 000 kg for sub-period 1 July to 31 August Carry over from previous sub-periods, for sub-period 1 September to 30 September
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- (4) in Annex VIII, in the table relating to the tariff quota with order number 09.4002, the row 'Quantity in kg' is replaced by the following:

'Quantity in kg'	10 500 000 kg product weight, divided as follows: the quantity available for each sub-period shall correspond to one twelfth of the total quantity
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- (5) Annex X is amended as follows:

- (a) in the table relating to the tariff quota with order number 09.4038, the row 'Quantity in kg' is replaced by the following:

'Quantity in kg'	5 720 000 kg product weight, divided as follows: 25 % for each sub-period
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- (b) the table relating to the tariff quota with order number 09.4170 is deleted.

ANNEX II

Annex I to Implementing Regulation (EU) 2020/1988 is amended as follows:

(1) the section under the heading 'Tariff quotas in the sector of cereals' is amended as follows:

(a) in the table relating to the tariff quota with order number 09.0073, the row 'Quantity' is replaced by the following:

'Quantity'	2 800 000 kg net weight'
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(b) in the table relating to the tariff quota with order number 09.0089, the row 'Quantity' is replaced by the following:

'Quantity'	1 732 000 kg net weight'
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(c) in the table relating to the tariff quota with order number 09.0070, the row 'Quantity' is replaced by the following:

'Quantity'	2 700 000 kg net weight'
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(2) in the section under the heading 'Tariff quotas in the sector of rice', in the table relating to the tariff quota with order number 09.0083, the row 'Quantity' is replaced by the following:

'Quantity'	7 000 kg'
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(3) the section under the heading 'Tariff quotas in the sector of fruits and vegetables' is amended as follows:

(a) in the table relating to the tariff quota with order number 09.0094, the row 'Quantity' is replaced by the following:

'Quantity'	472 000 kg'
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(b) in the table relating to the tariff quota with order number 09.0056, the row 'Quantity' is replaced by the following:

'Quantity'	1 244 000 kg'
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(c) in the table relating to the tariff quota with order number 09.0059, the row 'Quantity' is replaced by the following:

'Quantity'	647 000 kg'
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(d) in the table relating to the tariff quota with order number 09.0035, the row 'Quantity' is replaced by the following:

'Quantity'	9 770 000 kg'
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(e) in the table relating to the tariff quota with order number 09.0040, the row 'Quantity' is replaced by the following:

'Quantity'	151 000 kg'
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- (f) in the table relating to the tariff quota with order number 09.0041, the row 'Quantity' is replaced by the following:

'Quantity'	86 223 000 kg'
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- (4) in the section under the heading 'Tariff quotas in the sector of processed fruits and vegetables', in the table relating to the tariff quota with order number 09.0093, the row 'Quantity' is replaced by the following:

'Quantity'	6 551 000 kg'
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- (5) in the section under the heading 'Tariff quotas in the sector of milk and milk products', in the table relating to the tariff quota with order number 09.0147, the row 'Quantity' is replaced by the following:

'Quantity'	62 917 000 kg'
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- (6) in the section under the heading 'Tariff quotas in the sector of pigmeat', in the table relating to the tariff quota with order number 09.0123, the row 'Quantity' is replaced by the following:

'Quantity'	4 786 000 kg'
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- (7) in the section under the heading 'Tariff quotas in the sector of other products listed in Section 2 of Part XXIV of Annex I to Regulation (EU) No 1308/2013', in the table relating to the tariff quota with order number 09.0055, the row 'Quantity' is replaced by the following:

'Quantity'	4 295 000 kg'
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COMMISSION IMPLEMENTING REGULATION (EU) 2023/1143**of 9 June 2023****granting a Union authorisation for the single biocidal product ‘Chemisept IPA-N’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 24 April 2019, AS Chemi-Pharm submitted to the European Chemicals Agency (‘the Agency’) an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ⁽²⁾ for authorisation of the same single biocidal product, as referred to in Article 1 of that Regulation, named ‘Chemisept IPA-N’, of product-type 1, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-UU051173-14 in the Register for Biocidal Products (‘the Register’). The application also indicated the application number of the related reference biocidal product family ‘Knieler & Team Propanol Family’, recorded in the Register under case number BC-AQ050985-22.
- (2) The same single biocidal product ‘Chemisept IPA-N’ contains propan-1-ol and propan-2-ol as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 1.
- (3) On 8 December 2021, the Agency submitted to the Commission an opinion ⁽³⁾ and the draft summary of the biocidal product characteristics (‘SPC’) of ‘Chemisept IPA-N’ in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) The opinion concludes that the proposed differences between the same single biocidal product and the related reference biocidal product are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ⁽⁴⁾, and that based on the assessment of the related reference biocidal product family ‘Knieler & Team Propanol Family’ and subject to compliance with the draft SPC, the same single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.
- (5) On 24 October 2022, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same single biocidal product ‘Chemisept IPA-N’.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4).

⁽³⁾ ECHA opinion for ‘Chemisept IPA-N’, 8 December 2021, <https://echa.europa.eu/opinions-on-union-authorisation>

⁽⁴⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0027678-0000 is granted to AS Chemi-Pharm for the making available on the market and use of the same single biocidal product 'Chemisept IPA-N' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 2 July 2023 until 31 July 2032.

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, 9 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

Chemisept IPA-N

Product type 1 – Human hygiene (Disinfectants)

Authorisation number: EU-0027678-0000

R4BP asset number: EU-0027678-0000

1. ADMINISTRATIVE INFORMATION**1.1. Trade name(s) of the product**

Trade name(s)	Chemisept IPA-N
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Chemi-Pharm AS
	Address	Tänassilma tee 11, 76406 Tänassilma küla, Saku vald Estonia
Authorisation number	EU-0027678-0000	
R4BP asset number	EU-0027678-0000	
Date of the authorisation	2.7.2023	
Expiry date of the authorisation	31.7.2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	AS Chemi-Pharm
Address of manufacturer	Tänassilma tee 11, 76406 Tänassilma küla, Saku vald, Harju maakond Estonia
Location of manufacturing sites	AS Chemi-Pharm, Tänassilma tee 11, 76406 Tänassilma küla, Saku vald, Harju maakond Estonia

1.4. Manufacturer(s) of the active substance(s)

Active substance	Propan-1-ol
Name of manufacturer	OQ Chemicals GmbH (formerly Oxea GmbH)
Address of manufacturer	Rheinpromenade 4a, 40789 Monheim am Rhein Germany
Location of manufacturing sites	OQ Chemicals Corporation (formerly Oxea Corporation), 2001 FM 3057 TX, 77414 Bay City United States

Active substance	Propan-1-ol
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany
Location of manufacturing sites	BASF SE, Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany

Active substance	Propan-1-ol
Name of manufacturer	SASOL Chemie GmbH & Co. KG
Address of manufacturer	Secunda Chemical Operations, Sasol Place, 50 Katherine Street, 2090 Sandton South Africa
Location of manufacturing sites	Secunda Chemical Operations, PDP Kruger Street, 2302 Secunda South Africa

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvent Germany GmbH
Address of manufacturer	Römerstrasse 733, 47443 Moers Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany INEOS Solvent Germany GmbH, Shamrockstrasse 88, 44623 Herne Germany

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0

2.2. Type of formulation

AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
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Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of container to an authorised waste collection point.
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4. AUTHORISED USE(S)

4.1. Use description

Table 1

Use # 1 – hygienic handrub, liquid

Product type	PT01 – Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Mycobacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Enveloped viruses Development stage: no data
Field(s) of use	Indoor — hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients) — hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands — for professional use only
Application method(s)	Method: Manual application Detailed description: Rubbing

Application rate(s) and frequency	Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml) Contact time: 30 s Dilution (%): Ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100, 125, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.1.1. *Use-specific instructions for use*

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

4.2. **Use description**

Table 2

Use # 2 – surgical handrub, liquid

Product type	PT01 – Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant

Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Mycobacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: enveloped viruses Development stage: no data
Field(s) of use	Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.
Application method(s)	Method: Manual application Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 s Dilution (%): Ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional
Pack sizes and packaging material	100, 125, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.2.1. Use-specific instructions for use

The products can be applied directly or the products can be used in a dispenser or with a pump.

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾**

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

Keep out of reach of children.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible, show this sheet.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures:

Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

Prevent entry to sewers and public waters.

Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

5.4. Instructions for safe disposal of the product and its packaging

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0– 30 °C

Do not store at temperatures below 0 °C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. OTHER INFORMATION

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1144**of 9 June 2023****granting a Union authorisation for the single biocidal product 'Bacticide IPA-N' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 24 April 2019, Chemi-Pharm AS submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ⁽²⁾ for Union authorisation of the same single biocidal product, as referred to in Article 1 of that Regulation, named 'Bacticide IPA-N', of product-types 2 and 4, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-SM051156-28 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference biocidal product family 'Knieler & Team Propanol Family', recorded in the Register under case number BC-AQ050985-22.
- (2) The same single biocidal product 'Bacticide IPA-N' contains propan-1-ol and propan-2-ol as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 2 and 4.
- (3) On 8 December 2021, the Agency submitted to the Commission an opinion ⁽³⁾ and the draft summary of the biocidal product characteristics ('SPC') of 'Bacticide IPA-N' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.
- (4) The opinion concludes that the proposed differences between the same single biocidal product and the related reference biocidal product are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ⁽⁴⁾, and that based on the assessment of the related reference biocidal product family 'Knieler & Team Propanol Family' and subject to compliance with the draft SPC, the same single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.
- (5) On 24 October 2022, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same single biocidal product 'Bacticide IPA-N'.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4).

⁽³⁾ ECHA opinion for 'Bacticide IPA-N', 8 December 2021, <https://echa.europa.eu/opinions-on-union-authorisation>

⁽⁴⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0027679-0000 is granted to Chemi-Pharm AS for the making available on the market and use of the same single biocidal product 'Bacticid IPA-N' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 2 July 2023 until 31 July 2032.

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, 9 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

Bacticide IPA-N

Product type 2 – Disinfectants and algicides not intended for direct application to humans or animals
(Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0027679-0000

R4BP asset number: EU-0027679-0000

1. ADMINISTRATIVE INFORMATION**1.1. Trade name(s) of the product**

Trade name(s)	Bacticide IPA-N
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Chemi-Pharm AS
	Address	Tänassilma tee 11, 76406 Tänassilma küla, Saku vald Estonia
Authorisation number	EU-0027679-0000	
R4BP asset number	EU-0027679-0000	
Date of the authorisation	2.7.2023	
Expiry date of the authorisation	31.7.2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	AS Chemi-Pharm
Address of manufacturer	Tänassilma tee 11, 76406 Tänassilma küla, Saku vald, Harju maakond Estonia
Location of manufacturing sites	AS Chemi-Pharm, Tänassilma tee 11, 76406 Tänassilma küla, Saku vald, Harju maakond Estonia

1.4. Manufacturer(s) of the active substance(s)

Active substance	Propan-1-ol
Name of manufacturer	OQ Chemicals GmbH (formerly Oxea GmbH)
Address of manufacturer	Rheinpromenade 4a, 40789 Monheim am Rhein Germany
Location of manufacturing sites	OQ Chemicals Corporation (formerly Oxea Corporation), 2001 FM 3057 TX, 77414 Bay City United States

Active substance	Propan-1-ol
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany
Location of manufacturing sites	BASF SE, Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany

Active substance	Propan-1-ol
Name of manufacturer	SASOL Chemie GmbH & Co. KG
Address of manufacturer	Secunda Chemical Operations, Sasol Place, 50 Katherine Street, 2090 Sandton South Africa
Location of manufacturing sites	Secunda Chemical Operations, PDP Kruger Street, 2302 Secunda South Africa

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvent Germany GmbH
Address of manufacturer	Römerstrasse 733, 47443 Moers Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany INEOS Solvent Germany GmbH, Shamrockstrasse 88, 44623 Herne Germany

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	35,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	35,0

2.2. Type of formulation

AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking. Keep container tightly closed.

	Avoid breathing vapours. Use only outdoors or in a well-ventilated area. Wear eye protection.. IF INHALED:Remove person to fresh air and keep comfortable for breathing. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of container to an authorised waste collection point.
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4. AUTHORISED USE(S)

4.1. Use description

Table 1

Use # 1 – hard non-porous small surface disinfection RTU liquid

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: viruses (limited spectrum virucidal activity) Development stage: no data
Field(s) of use	Indoor Health care facilities and pharmaceutical and cosmetic industry, for example patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20 ± 2 °C). The entire surface to be disinfected is wetted by pouring or spraying from a short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m² to keep the surface wet during the contact time.

Application rate(s) and frequency	Application Rate: Minimum exposure time: — for the control of bacteria, yeasts and enveloped viruses: 60 sec — for the control of viruses (limited spectrum virucidal activity): 5 min Dilution (%): Ready-to-use product Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100, 500, 750 and 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.1.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use

4.2. **Use description**

Table 2

Use # 2 – hard non-porous small surface disinfection RTU liquid

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data

Field(s) of use	Indoor Health care facilities and in food industry, for example food preparation and handling in kitchens/restaurants: disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20 ± 2 °C). The entire surface to be disinfected is wetted by pouring or spraying from a short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m ²) to keep the surface wet during the contact time.
Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria and yeasts at 20 °C: 60 sec Dilution (%): Ready-to-use product Number and timing of application: The products can be used as often as necessary. A reasonable frequency in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100, 500, 750 and 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.2.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use.

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾**

5.1. **Instructions for use**

For professional use only.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

5.2. Risk mitigation measures

The use of eye protection during handling of the product is mandatory.

Keep out of reach of children

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible, show this sheet.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking. Prevent entry to sewers and public waters. Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

5.4. Instructions for safe disposal of the product and its packaging

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0– 30 °C

Do not store at temperatures below 0 °C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. OTHER INFORMATION

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2023/1145

of 7 June 2023

amending Implementing Decision (EU) 2022/2333 concerning certain emergency measures relating to sheep pox and goat pox in Spain

(notified under document C(2023)3806)

(Only the Spanish text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Article 259(1) thereof,

Whereas:

- (1) Commission Implementing Decision (EU) 2022/2333 ⁽²⁾ was adopted within the framework of Regulation (EU) 2016/429, and it lays down emergency measures relating to outbreaks of sheep pox and goat pox in Spain, that were detected in the regions of Andalusia and Castilla-La Mancha, where they form two distinct clusters, one in each region. That Implementing Decision applies until 31 October 2023.
- (2) More particularly, Implementing Decision (EU) 2022/2333 provides that the protection, surveillance and further restricted zones, to be established by Spain following outbreaks of sheep pox and goat pox, in accordance with Article 21 of Commission Delegated Regulation (EU) 2020/687 ⁽³⁾, are to comprise at least the areas listed in the Annex to that Implementing Decision.
- (3) In addition to the protection and surveillance zones, a further restricted zone was established, in accordance with Article 21(1), point (c), of Delegated Regulation (EU) 2020/687, in both the regions of Andalusia and Castilla-La Mancha, where Spain is required to apply certain measures regarding restrictions on the movements of sheep and goats outside that further restricted zone, with a view to preventing the spread of sheep pox and goat pox to the rest of its territory and to the rest of the Union.
- (4) After the adoption of Implementing Decision (EU) 2022/2333, Spain notified the Commission of a number of additional outbreaks of sheep pox and goat pox in establishments where sheep and/or goats were kept. As a result, the areas listed as protection and surveillance zones, as well as the areas listed as further restricted zones for Spain, in the Annex to Implementing Decision (EU) 2022/2333, were subsequently amended. The last amendment to that Annex was made by the Commission Implementing Decision 2023/872 ⁽⁴⁾.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Implementing Decision (EU) 2022/2333 of 23 November 2022 concerning certain emergency measures relating to sheep pox and goat pox in Spain and repealing Implementing Decision (EU) 2022/1913 (OJ L 308, 29.11.2022, p. 22).

⁽³⁾ Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

⁽⁴⁾ Commission Implementing Decision (EU) 2023/872 of 20 April 2023 amending Implementing Decision (EU) 2022/2333 concerning certain emergency measures relating to sheep pox and goat pox in Spain (OJ L 113, 28.4.2023, p. 49).

- (5) Since the date of adoption of Implementing Decision (EU) 2023/872, Spain has notified the Commission of one additional outbreak of sheep pox and goat pox in establishments where sheep and/or goats were kept, in the region of Castilla-La Mancha, more specifically in the Province of Cuenca, outside the surveillance zone already established in that region.
- (6) The competent authority of Spain has taken the necessary disease control measures required in accordance with Delegated Regulation (EU) 2020/687, including the establishment of protection and surveillance zones around the new outbreak. Spain has also maintained the previously established restricted zones, around the previous outbreaks, recorded since the beginning of 2023 in Castilla-La Mancha, in the Province of Ciudad Real.
- (7) Therefore, the areas listed as protection, surveillance and further restricted zones for Spain in the Annex to Implementing Decision (EU) 2022/2333 should be amended, spatially and temporally, taking into account the current epidemiological situation as regards sheep pox and goat pox in the region of Castilla-La Mancha.
- (8) Given the urgency of the epidemiological situation in the Union as regards the spread of sheep pox and goat pox, it is important that the amendments to be made to the Annex to Implementing Decision (EU) 2022/2333 by this Decision take effect as soon as possible.
- (9) In addition, taking into account the current epidemiological situation in the Union as regards sheep pox and goat pox, the period of application of Implementing Decision (EU) 2022/2333 should be prolonged until 31 December 2023.
- (10) Implementing Decision (EU) 2022/2333 should therefore be amended accordingly.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Amendments to Implementing Decision (EU) 2022/2333

Implementing Decision (EU) 2022/2333 is amended as follows:

1. Article 5 is replaced by the following:

'Article 5

Application

This Decision shall apply until 31 December 2023.';

2. the Annex to Implementing Decision (EU) 2022/2333 is replaced by the text set out in the Annex to this Decision.

Article 2

Addressee

This Decision is addressed to the Kingdom of Spain.

Done at Brussels, 7 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

‘ANNEX

A. Protection and surveillance zones established around confirmed outbreaks

Region and ADIS reference number of the outbreak	Areas established as protection and surveillance zones, part of the restricted zones in Spain as referred to in Article 1	Date until applicable
Region of Castilla-La Mancha ES-CAPRIPOX-2023-00003 ES-CAPRIPOX-2023-00004 ES-CAPRIPOX-2023-00005 ES-CAPRIPOX-2023-00006 ES-CAPRIPOX-2023-00007	Protection zone: A protection zone that comprises the following areas: In the province of Ciudad Real the municipalities of: — Alcázar de San Juan — Campo de Criptana — Pedro Muñoz In the province of Albacete the municipality of: — Minaya In province of Cuenca the municipalities of: — Sisante — Casas de Fernando Alonso — Casas de Haro — Casas de los Pinos — El Pedernoso — El Provencio — Las Mesas — Las Pedroñeras — Mota del Cuervo — Pozoamargo — San Clemente — Santa María de los Llanos — Vara de Rey	20.7.2023
	Surveillance zone: A surveillance zone that comprises the following areas: In the province of Ciudad Real the municipalities of: — Villarta de San Juan — Villarrubia de los Ojos — Tomelloso — Socuéllamos — Puerto Lápice — Manzanares — Llanos de Caudillo — Las Labores — Herencia — Daimiel	7.8.2023

	— Argamasilla de Alba — Arenas de San Juan — Arenales de San Gregorio In the province of Toledo the municipalities of: — Villafranca de los Caballeros — Villacañas — Quintanar de la Orden — Quero — Miguel Esteban — Madridejos — La Villa de Don Fabrique — La Puebla de Almoradiel — El Toboso — Camuñas In the province of Cuenca the municipalities of: — Atalaya del Cañavate — Cañada Juncosa — El Cañavate — Honrubia — Pinarejo — Alarcón — Casas de Benítez — Casas de Guijarro — Casasimarro — El Picazo — Pozorrubielos de la Mancha — Quintanar del Rey — Tébar — Valhermoso de la Fuente — Villanueva de la Jara — Belmonte — Carrascosa de Haro — La Alberca de Zánacara — Los Hinojosos — Monreal del Llano — Rada de Haro — Santa María del Campo Rus — Villaescusa de Haro (only the exclave of Dehesa de Alcahozo) In the province of Albacete the municipalities of: — Fuensanta — La Roda — Munera — Tarazona de la Mancha — Villalgordo del Júcar — Villarrobledo	
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	Surveillance zone: A surveillance zone that comprises the following areas: In the province of Ciudad Real the municipalities of: — Alcázar de San Juan — Campo de Criptana — Pedro Muñoz In the province of Albacete the municipality of: — Minaya In province of Cuenca the municipalities of: — Sisante — Casas de Fernando Alonso — Casas de Haro — Casas de los Pinos — El Pedernoso — El Provencio — Las Mesas — Las Pedroñeras — Mota del Cuervo — Pozoamargo — San Clemente — Santa María de los Llanos — Vara de Rey	21.7.2023-7.8.2023
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B. Further restricted zones

Region	Areas established as further restricted zones, part of the restricted zones in Spain as referred to in Article 1	Date until applicable
Region of Castilla–La Mancha	A further restricted zone that comprises the following provinces: — Albacete — Ciudad Real — Cuenca — Toledo	25.9.2023'

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2023 OF THE JOINT COMMITTEE ESTABLISHED BY THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE UNITED STATES OF AMERICA

of 26 May 2023

on the mutual recognition of certificates of conformity for marine equipment amending Annexes I, II and III [2023/1146]

THE JOINT COMMITTEE,

Having regard to the Agreement between the European Community and the United States of America on the mutual recognition of certificates of conformity for marine equipment, and in particular Article 7 thereof;

Whereas:

- (1) Pursuant to Article 7(3)(d) of the Agreement between the European Community and the United States of America on the mutual recognition of certificates of conformity for marine equipment ('the Agreement'), the Joint Committee established under Article 7(1) of the Agreement may amend the Annexes thereto.
- (2) In order to support the proper implementation of the legislation that is within the scope of the Agreement it is important to include interpretations developed by the notified body coordination group established under Directive 2014/90/EU of the European Parliament and of the Council ⁽¹⁾ as well as policy guidance issued by the U. S. Coast Guard in the list of laws, regulations and administrative provisions listed in Annex I.
- (3) Therefore, Annex I to the Agreement should be amended accordingly.
- (4) In accordance with Article 7(3)(a) of the Agreement, the Joint Committee is responsible for developing and maintaining the list in Annex II of products and associated legislative, regulatory and administrative provisions that the Parties have determined to be equivalent.
- (5) Taking into account technical progress and changes to the international instruments, the European Union and the United States of America have agreed on the modification of the product coverage for mutual recognition.
- (6) Therefore, Annex II of the Agreement should be amended accordingly.
- (7) The list of regulatory authorities and their addresses should be updated and the regulatory authority of the United Kingdom should be removed.
- (8) Therefore, Annex III of the Agreement should be amended accordingly,

⁽¹⁾ Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146).

HAS DECIDED AS FOLLOWS:

Annexes I, II and III of the Agreement are replaced by the text in the Annex to this Decision.

This Decision, done in duplicate, shall be signed by representatives of the Joint Committee who are authorised to act on behalf of the Parties for purposes of amending the Agreement. This Decision shall be effective from the date of the later of these signatures.

On behalf of the United States of America

Sushan DEMIRJIAN

Signed in Brussels, on 26 May 2023

On behalf of the European Union

Lucian CERNAT

Signed in Brussels, on 26 May 2023

ANNEX

'ANNEX I

LEGISLATION, REGULATIONS AND ADMINISTRATIVE PROVISIONS

EU legislation, regulations and administrative provisions:

- Directive 2014/90/EU (hereinafter referred to as 'MED') and the implementing acts adopted in accordance with Articles 35(2) and (3) of that Directive, which are published in the Official Journal of the European Union and made available on <https://portal.med.emsa.europa.eu/>.
- Guidelines for the implementation of, in particular, conformity assessment procedures falling under the MED are provided by:
 - The 'Blue Guide' on the implementation of EU product rules 2022; and
 - Interpretations developed by the notified body coordination group established under Directive 2014/90/EU (MarED), approved by the Committee on Safe Seas and prevention of pollution from ships established under Council Regulation (EC) No 2099/2002 (COSS) and made available to the public on <https://portal.med.emsa.europa.eu/>.

U.S. legislation, regulations and administrative provisions:

- United States Code, Title 46 (46 U.S.C. 3306), provides statutory authority to the United States Coast Guard (through delegation by the Secretary of the Department of Homeland Security) to issue regulations for approval of marine equipment.
- United States Code of Federal Regulations
 - Title 46, Subpart 2.75 and Part 159, related to the authorities and procedures for U.S. Coast Guard approval of marine equipment;
 - Title 46, Parts 160 to 164, for lifesaving equipment, electrical equipment, engineering systems;
 - Title 47, Part 80 for radio equipment. Equipment which includes a radio transmitter is regulated by the U.S. Federal Communications Commission (FCC) and requires FCC type-certification before such equipment may be marketed, sold or used in the United States. These items are identified by § in Annex II.
- Policy guidance issued by the U.S. Coast Guard
 - Navigation and Vessel Inspection Circular (NVIC) 02-19 pertaining to approvals issued by the U.S. Coast Guard under the MRA;
 - NVIC 08-01, for approval of navigation equipment;
 - Additional guidance posted on: <https://www.dco.uscg.mil/CG-ENG-4/Equipment/>.

ANNEX II

PRODUCT COVERAGE FOR MUTUAL RECOGNITION

Lifesaving appliances

Product item identification	EU item number	U.S. item
Position- indicating lights for life- saving appliances: for survival craft and rescue boats	MED/1.2a	161.101
Position- indicating lights for life- saving appliances: for lifebuoys	MED/1.2b	161.110
Position- indicating lights for life- saving appliances: for lifejackets	MED/1.2c	161.112
Lifebuoy self- activating smoke signals Note: Expiration date not to exceed 48 months after month of manufacture.	MED/1.3	160.157
Rocket parachute flares (pyrotechnics) Note: Expiration date not to exceed 48 months after month of manufacture.	MED/1.8	160.136
Hand flares (pyrotechnics) Note: Expiration date not to exceed 48 months after month of manufacture.	MED/1.9	160.121
Buoyant smoke signals (pyrotechnics) Note: Expiration date not to exceed 48 months after month of manufacture.	MED/1.10	160.122
Line-throwing appliances Note: Expiration date not to exceed 48 months after month of manufacture.	MED/1.11	160.040
Rigid liferafts Note: The emergency pack is not covered by the Agreement	MED/1.13	160.118
Automatically self- righting liferafts (rigid liferafts only/inflatable liferafts not covered) Note: The emergency pack is not covered by the Agreement	MED/1.14b	160.118
Canopied reversible liferafts (rigid liferafts only/inflatable liferafts not covered) Note: The emergency pack is not covered by the Agreement	MED/1.15	160.118
Float- free arrangements for liferafts (hydrostatic release units)	MED/1.16	160.162
Release mechanism for: Lifeboats and rescue boats (launched by a fall or falls) Limited to Davit-launched liferaft automatic release hook	MED/1.26a	160.170

Product item identification	EU item number	U.S. item
Release mechanism for: Liferafts (launched by a fall or falls) Limited to Davit-launched liferaft automatic release hook	MED/1.26b	160.170
Marine evacuation systems	MED/1.27	160.175
Embarkation Ladders	MED/1.29	160.117
Retro-reflective materials	MED/1.30	164.018

Fire protection

Product item identification	EU item number	U.S. item number
Primary deck coverings	MED/3.1	164.106
'A' & 'B' Class divisions fire integrity: 'A' class divisions: A-60 deck assemblies	MED/3.11a	164.105
'A' & 'B' Class divisions fire integrity: 'A' class divisions: A-60 structural insulation	MED/3.11a	164.107
'A' & 'B' Class divisions fire integrity: 'B' class divisions. - bulkheads.	MED/3.11b	164.108
'A' & 'B' Class divisions fire integrity: 'B' class divisions. - ceilings.	MED/3.11b	164.110
Non-combustible materials	MED/3.13	164.109
Fire doors Limited to fire doors without windows or with total window area no more than 645 cm ² in each door leaf, unless hose stream, heat flux, and/or temperature rise tests are conducted according to USCG approval guidance. Approval limited to maximum door size tested. Doors must be used with a fire tested frame design.	MED/3.16	164.136
Fire door control systems components.	MED/3.17	164.146
Surface materials and floor coverings with low flame-spread characteristics: decorative veneers.	MED/3.18a	164.112
Surface materials and floor coverings with low flame-spread characteristics: paint systems.	MED/3.18b	164.112
Surface materials and floor coverings with low flame-spread characteristics: floor coverings.	MED/3.18c	164.117
Surface materials and floor coverings with low flame-spread characteristics: combustible ducts membrane.	MED/3.18f	164.112

Product item identification	EU item number	U.S. item number
Draperies, curtains and other suspended textile materials and films	MED/3.19	164.111
Upholstered furniture: Cover material for flame-retardant filling material	MED/3.20b	164.144
Upholstered furniture: Cover material for flame-retardant filling material (tested in specific combination as intended for the later application).	MED/3.20c	164.144
Bedding components	MED/3.21	164.142
Fire dampers	MED/3.22	164.139
Penetrations through 'A' class electric cable transits.	MED/3.26a	164.138
Penetrations through 'A' class pipe, duct, trunk, etc. penetrations	MED/3.26b	164.138
Fire restricting materials (except furniture) for high-speed craft	MED/3.32	164.201
Fire restricting materials for furniture for high-speed craft	MED/3.33	164.201
Fire resisting divisions for high-speed craft	MED/3.34	164.207
C class divisions	MED/3.64	164.109

Navigation equipment

Product item identification	EU item	US item number
Magnetic compass Class A for ships	MED/4.1	165.101
Transmitting heading device THD (magnetic method)	MED/4.2	165.102
Echo-sounding equipment	MED/4.6	165.107
Speed and distance measuring equipment (SDME)	MED/4.7	165.105
Rate- of- turn- indicator	MED/4.9	165.106
Heading control system (HCS)	MED/4.16	165.110
Rudder Angle Indicator	MED/4.20	165.167
Propeller revolution indicator	MED/4.21	165.168
Pitch Indicator	MED/4.22	165.169
Voyage data recorder (VDR)	MED/4.29	165.150
Electronic chart display and information system (ECDIS) with backup, and raster chart display system (RCDS)	MED/4.30	165.123 165.124
Universal automatic identification system equipment (AIS)	MED/4.32	165.155
Track control system (working at ship's speed from minimum manoeuvring speed up to 30 knots)	MED/4.33	165.112

Product item identification	EU item	US item number
Radar reflector passive type	MED/4.39	165.160
Heading control system for high-speed craft	MED/4.40	165.210
Transmitting heading device THD (GNSS method)	MED/4.41	165.102
Searchlight for high-speed craft	MED/4.42	165.252
Night vision equipment for high-speed craft	MED/4.43	165.251
Transmitting heading device THD (Gyroscopic method)	MED/4.46	165.102
Simplified voyage data recorder (S- VDR)	MED/4.47	165.151
Pilot ladder	MED/4.49	163.003
Daylight signaling lamp	MED/4.52	165.166
Bridge Navigational Watch Alarm System (BNWAS)	MED/4.57	165.142
Sound reception system	MED/4.58	165.165
Integrated navigation system	MED/4.59	165.141
GPS equipment	MED/4.63	165.130
GLONASS equipment	MED/4.63	165.131
DGPS equipment	MED/4.63	165.132
DGLONASS equipment	MED/4.63	165.133
Radar equipment CAT 1 (Radar equipment used with ARPA must have separate EU and USA certifications) [†]	MED/4.64	165.115
Radar equipment CAT 2 (Radar equipment used with ATA must have separate EU and USA certifications) [†]	MED/4.64	165.116
Radar equipment CAT 3 (Radar equipment used with EPA must have separate EU and USA certifications) [†]	MED/4.64	165.117
Radar equipment for high-speed craft applications (CAT 1H) [†]	MED/4.64	165.216
Radar equipment for high-speed craft applications (CAT 2H) [†]	MED/4.64	165.217
Gyro compass	MED/4.65	165.103
Gyro compass for high-speed craft	MED/4.65	165.203'

‘ANNEX III

REGULATORY AUTHORITIES

EUROPEAN UNION

Belgium	SPF Mobilité (FPS Mobility) Rue du Progrès 56 1210 Bruxelles
	FOD Mobiliteit (FPS Mobility) Vooruitgangstraat 56 1210 Brussel
Bulgaria	Министерство на транспорта, информационните технологии и съобщенията ул. "Дякон Игнатий" № 9 София 1000,
	Ministry of Transport, Information Technology and Communications 9, Dyakon Ignatij str. Sofia 1000
Czech Republic	Ministerstvo dopravy (Ministry of Transport) P.O. Box 9 Nábřeží Ludvíka Svobody 12 110 15 Praha 1
Denmark	Erhvervsministeriet (Ministry of Industry, Business and Financial Affairs) Slotsholmsgade 10-12 DK-1216 Copenhagen K
Germany	Bundesministerium für Verkehr und digitale Infrastruktur (Ministry of Transport and Digital Infrastructure) Invalidenstr. 44, 10115 Berlin
Estonia	Majandus- ja Kommunikat- siooniministeerium (Ministry of Economic Affairs and Infrastructure) Suur- Ameerika 1 10122 Tallinn
Ireland	Department of Transport Leeson Lane Dublin D02 TR60
	An Roinn Iompair Lána Liosáin Baile Átha Cliath D02 TR60
Greece	Υπουργείο Ναυτιλίας & Νησιωτικής Πολιτικής Ακτι Βασιλειάδη, Πύλη Ε 1 - Ε 2, Τ.Κ. 185 10, Πειραιάς
	Ministry of Shipping and Island Policy Akti Vassiliadi, Gates E1- E2 18510 Piraeus
Spain	Ministerio de Fomento (Ministry of Public Works) Paseo de la Castellana, 67 28071 Madrid

France	Ministère de la transition écologique et solidaire 246, Boulevard St. Germain 75007 Paris
Croatia	Ministarstvo mora, prometa i infrastrukture (Ministry of the Sea, Transport and Infrastructure) Prisavlje 14, 10 000 Zagreb
Italy	Ministero delle Infrastrutture e dei Trasporti (Ministry for Infrastructure and Transport) Piazzale di Porta Pia 1 00198 Roma
Cyprus	Υπουργείο Μεταφορών, Επικοινωνιών και Έργων Αχαιών 28, 1424 Λευκωσία Ministry of Transport, Communications and Works Axaion 28 1424 Nicosia
Latvia	Satiksmes ministrija (Ministry for Transport and Communications) Gogola iela 3, Riga 1743
Lithuania	Susisiekimo ministerija (Ministry of Transport and Communications) Gedimino av. 17 01505 Vilnius
Luxembourg	Ministère du Développement durable et des Infrastructures 4, Place de l'Europe 1499 Luxembourg
Hungary	Nemzeti Fejlesztési Minisztérium (Ministry of National Development) Fő u. 44- 50. 1011 Budapest
Malta	Ministeru għat- Trasport, Infrastruttura u Proġetti Kapitali/ Ministry for Transport, Infrastructure and Capital Projects Triq Francesco Buonamici Floriana FRN1700
Netherlands	Ministerie van Infrastructuur en Waterstaat (Ministry of Infrastructure and Water Management) Rijnstraat 8, 2515 XP 's Gravenhage Postbus 20901 2500 EX's Gravenhage
Austria	Bundesministerium für Verkehr, Innovation und Technologie (Ministry for Transport, Innovation and Technology) Radetzkystraße 2 1030 Wien
Poland	Ministerstwo Infrastruktury (Ministry of Infrastructure and Construction) ul. Chałubińskiego 4/6 00 928 Warszawa
Portugal	Direção-Geral de Recursos Naturais, Segurança e Serviços Marítimos (Directorate-General for Natural Resources, Safety and Maritime Services) Av. Brasília 1449- 030 Lisboa

Romania	Ministerul Transporturilor (Ministry of Transport) 38, Blvd. Dinicu Golescu Sector 1 – București
Slovenia	Ministrstvo za infrastrukturo (Ministry of Infrastructure) Langusova 4 SI-1535 Ljubljana
Slovakia	Ministerstvo dopravy a výstavby (Ministry of Transport and Construction) Námestie slobody 6 810 05 Bratislava
Finland	Liikenne- ja viestintäministeriö (Ministry of Transport and Communications) Eteläesplanadi 16, Helsinki P.O. Box 31 00023 Government Kommunikationsministeriet (Ministry of Transport and Communications) Södra esplanaden 16, Helsingfors PB 31, 00023 Statsrådet
Sweden	Närings-departementet (Ministry of Enterprise and Innovation) Mäster Samuelsgatan 70, Stockholm 103 33 Stockholm
European Commission	Directorate General Mobility and Transport (DG MOVE) Maritime Safety Unit 200, rue de la Loi 1049 Brussels, Belgium
UNITED STATES OF AMERICA	United States Coast Guard Office of Design and Engineering Standards (CG- ENG) 2703 Martin Luther King Jr Ave SE STOP 7509 Washington DC 20593-7509

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