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Legislation

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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 IMPLEMENTING REGULATION (EU) 2022/8

of 6 January 2022

amending for the 326th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations ⁽¹⁾, and in particular Article 7(1)(a) and Article 7a(5) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.
- (2) On 3 January 2022, the Sanctions Committee of the United Nations Security Council decided to remove five entries from the list of persons, groups and entities to whom the freezing of funds and economic resources should apply.
- (3) Annex I to Regulation (EC) No 881/2002 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 6 January 2022.

⁽¹⁾ OJ L 139, 29.5.2002, p. 9.

*For the Commission,
On behalf of the President,
Director-General
Directorate-General for Financial Stability, Financial
Services and Capital Markets Union*

ANNEX

In Annex I to Regulation (EC) No 881/2002, the following entries under the heading 'Natural persons' are deleted:

- (1) 'Mevlüt Kar (alias (a) Mevluet Kar, (b) Abu Obaidah, (c) Obeidah Al Turki, (d) Al-Turki, (e) Al Turki Kyosev, (f) Yanal Yusov, (g) Abu Udejf el-Turki, (h) Abu Obejd el-Turki, (i) Abdurrahman Almanci). Date of birth: 25.12.1978. Place of birth: Ludwigshafen, Germany. Nationality: Turkish. Passport No: TR-M842033 Turkish passport issued on 2 May 2002 in Mainz, Germany by the Turkish Consulate General, expired on 24 Jul. 2007). Other information: (a) Previous address (as at August 2009): Güngören Merkez Mahallesi Toros Sokak 6/5, Istanbul, Turkey; (b) Associated with Islamic Jihad Group. Date of designation referred to in Article 2a(4)(b): 25.1.2012.'
 - (2) 'Denis Mamadou Gerhard Cuspert (alias Abu Talha al-Almani). Date of birth: 18.10.1975. Place of birth: Berlin, Germany. Nationality: German. National identification no.: 2550439611 (German national identification number, issued in District Friedrichshain-Kreuzberg of Berlin, Germany, issued on 22.4.2010, expires on 21.4.2020). Address: Karl-Marx-Str. 210, 12055 Berlin, Germany. Other information: (a) Physical description: eye colour: brown; hair colour: black; height: 178cm. Tattoos: BROKEN DREAMS in letters (on back) and landscape of Africa (on right upper arm); (b) Father's name: Richard Luc-Giffard; (c) Mother's name: Sigrid Cuspert; (d) Located at Syria/Turkey area (as at January 2015). Date of designation referred to in Article 2a(4)(b): 10.2.2015.'
 - (3) 'Nayef Salam Muhammad Ujaym Al-Hababi (alias (a) Nayf Salam Muhammad Ujaym al-Hababi, (b) Faruq al-Qahtani, (c) Faruq al-Qatari, (d) Farouq al-Qahtani al Qatari, (e) Sheikh Farooq al-Qahtani, (f) Shaykh Imran Farouk, (g) Sheikh Farooq al-Qatari). Date of birth: (a) 1981, (b) Approximately 1980. Place of birth: Saudi Arabia. Nationality: (a) Saudi Arabia, (b) Qatar. Passport No: 592667 (Qatari passport issued on 3 May 2007). Address: Afghanistan (since 2009). Date of designation referred to in Article 7d(2)(i): 28.3.2016.'
 - (4) 'Turki Mubarak Abdullah Ahmad Al-Binali (alias (a) Turki Mubarak Abdullah Al Binali, (b) Turki Mubarak al-Binali (c) Turki al-Benali, (d) Turki al-Binali, (e) Abu Human Bakr ibn Abd al-Aziz al-Athari, (f) Abu Bakr al-Athari, (g) Abu Hazm al-Salafi (h) Abu Hudhayfa al-Bahrayni, (i) Abu Khuzayma al-Mudari, (j) Abu Sufyan al-Sulami, (k) Abu Dergham, (l) Abu Human al-Athari). Date of birth: 3.9.1984. Place of birth: Al Muharraaq, Bahrain. Nationality: Bahrain (citizenship revoked in January 2015). Passport No: (a) 2231616 Bahraini Passport number issued on 2.1.2013 expires on 2.1.2023, (b) 1272611 Bahraini Passport number previous, issued on 1.4.2003, (c) 840901356 National identification No. Date of designation referred to in Article 7d(2)(i): 20.4.2016.'
 - (5) 'Tuah Febriwansyah (alias (a) Tuah Febriwansyah bin Arif Hasrudin, (b) Tuwah Febriwansah (c) Muhammad Fachri (d) Muhammad Fachria (e) Muhammad Fachry). Date of birth: 18.2.1968. Place of birth: Jakarta, Indonesia. Nationality: Indonesia. Address: Jalan Baru LUK, No 1, RT 05/07, Kelurahan Bhakti Jaya, Setu Sub-district, Pamulang District, Tangerang Selatan, Banten Province, Indonesia. Indonesian National Identity Card number 09.5004.180268.0074. Date of designation referred to in Article 7d(2)(i): 20.4.2016.'
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DECISIONS

COUNCIL DECISION (EU) 2022/9

of 2 December 2021

on the position to be taken on behalf of the European Union at the 22nd meeting of the Contracting Parties to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (Barcelona Convention) and its Protocols as regards the adoption of a decision to amend the Annex to the Protocol for the Prevention and Elimination of Pollution of the Mediterranean Sea by Dumping from Ships and Aircraft or Incineration at Sea (Dumping Protocol)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Protocol to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean ('the Barcelona Convention') for the Prevention and Elimination of Pollution of the Mediterranean Sea by Dumping from Ships and Aircraft or Incineration at Sea ('the Dumping Protocol') was concluded by the Union by means of Council Decision 77/585/EEC ⁽¹⁾ and entered into force on 15 April 1978.
- (2) Pursuant to Article 18(2), point (iii), of the Barcelona Convention, the meeting of the Contracting Parties to the Barcelona Convention and its Protocols is to adopt amendments to the annexes to the Protocols to the Convention.
- (3) During their 22nd meeting from 7 to 10 December 2021, the Contracting Parties to the Barcelona Convention and its Protocols are expected to adopt a decision ('the Decision of the Contracting Parties') amending the Annex to the Dumping Protocol on the factors to be considered in establishing criteria governing the issue of permits for the dumping of matter at sea taking into account Article 6 of the Dumping Protocol.
- (4) The Decision of the Contracting Parties relates to the protection of the environment, which is a shared competence between the Union and its Member States under Article 4(2), point (e), of the Treaty. The Decision of the Contracting Parties does not fall within an area which is largely covered by Union rules concerning such protection. The Union does not intend to make use of the possibility of exercising its external competence with regard to areas covered by the Decision of the Contracting Parties in relation to which its competence has not yet been exercised internally.
- (5) It is appropriate to establish the position to be taken on the Union's behalf at the meeting of the Contracting Parties to the Barcelona Convention and its Protocols, as the Decision of the Contracting Parties concerns the adoption of amendments to the Annex to the Dumping Protocol that will be binding on the Union.

⁽¹⁾ Council Decision 77/585/EEC of 25 July 1977 concluding the Convention for the protection of the Mediterranean Sea against pollution and the Protocol for the prevention of the pollution of the Mediterranean Sea by dumping from ships and aircraft (OJ L 240, 19.9.1977, p. 1).

- (6) Since the envisaged amendments to the Annex to the Dumping Protocol will update requirements regarding the protection of the Mediterranean Sea, affect the Union's international commitments and ambitions and improve the protection of the environment, the Union should support the adoption of the Decision of the Contracting Parties,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols shall be to support the adoption of a decision amending the Annex to the Protocol for the Prevention and Elimination of Pollution of the Mediterranean Sea by Dumping from Ships and Aircraft or Incineration at Sea.

Article 2

In the light of developments at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols, refinement of the position referred to in Article 1 may be agreed to by the representatives of the Union, in consultation with Member States, during on-the-spot coordination meetings without a further decision of the Council.

Article 3

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

Done at Brussels, 2 December 2021.

For the Council
The President
J. VRTOVEC

COUNCIL DECISION (EU) 2022/10**of 2 December 2021****on the position to be taken on behalf of the European Union at the 22nd meeting of the Contracting Parties to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (Barcelona Convention) and its Protocols as regards the adoption of a decision to amend Annexes I, II and IV to the Protocol for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources and Activities (LBS Protocol)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The amended Protocol to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean ('the Barcelona Convention') for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources and Activities ('the LBS Protocol') was concluded by the Union by means of Council Decision 1999/801/EC ⁽¹⁾ and entered into force on 11 May 2008.
- (2) Pursuant to Article 18(2), point (iii), of the Barcelona Convention, the meeting of the Contracting Parties to the Barcelona Convention and its Protocols is to adopt amendments to the annexes to the Protocols to the Convention.
- (3) During their 22nd meeting from 7 to 10 December 2021, the Contracting Parties to the Barcelona Convention and its Protocols are expected to adopt a decision ('the Decision of the Contracting Parties') amending Annexes I, II and IV to the LBS Protocol to take into account regulatory, scientific and technical developments related to land-based sources and activities that have been achieved at both global and regional levels.
- (4) The Decision of the Contracting Parties relates to the protection of the environment, which is a shared competence between the Union and its Member States under Article 4(2), point (e), of the Treaty. The Decision of the Contracting Parties does not fall within an area which is largely covered by Union rules concerning such protection. The Union does not intend to make use of the possibility of exercising its external competence with regard to areas covered by the Decision of the Contracting Parties in relation to which its competence has not yet been exercised internally.
- (5) It is appropriate to establish the position to be taken on the Union's behalf at the meeting of the Contracting Parties to the Barcelona Convention and its Protocols, as the Decision of the Contracting Parties concerns the adoption of amendments to Annexes I, II and IV to the LBS Protocol that will be binding on the Union.
- (6) Since the envisaged amendments to Annexes I, II and IV to the LBS Protocol will update requirements regarding the protection of the Mediterranean Sea, affect the Union's international commitments and ambitions and improve the protection of the environment, the Union should support the adoption of the Decision of the Contracting Parties,

⁽¹⁾ Council Decision 1999/801/EC of 22 October 1999 on accepting the amendments to the Protocol for the protection of the Mediterranean Sea against pollution from land-based sources (Barcelona Convention) (OJ L 322, 14.12.1999, p. 18).

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols shall be to support the adoption of a decision amending Annexes I, II and IV to the Protocol for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources and Activities.

Article 2

In the light of developments at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols, refinement of the position referred to in Article 1 may be agreed to by the representatives of the Union, in consultation with Member States, during on-the-spot coordination meetings without a further decision of the Council.

Article 3

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

Done at Brussels, 2 December 2021.

For the Council
The President
J. VRTOVEC

COUNCIL DECISION (EU) 2022/11**of 2 December 2021**

on the position to be taken on behalf of the European Union at the 22nd meeting of the Contracting Parties to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (Barcelona Convention) and its Protocols as regards the adoption of a decision to amend Annexes I, II, III and IV and Annex VII, section A, to the Protocol for the Protection of the Mediterranean Sea against Pollution Resulting from Exploration and Exploitation of the Continental Shelf and the Seabed and its Subsoil (Offshore Protocol)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Protocol to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean ('the Barcelona Convention') for the Protection of the Mediterranean Sea against Pollution Resulting from Exploration and Exploitation of the Continental Shelf and the Seabed and its Subsoil ('the Offshore Protocol') was concluded by the Union by means of Council Decision 2013/5/EU ⁽¹⁾ and entered into force on 29 March 2013.
- (2) Pursuant to Article 18(2), point (iii), of the Barcelona Convention, the meeting of the Contracting Parties to the Barcelona Convention and its Protocols is to adopt amendments to the annexes to the Protocols to the Convention.
- (3) During their 22nd meeting from 7 to 10 December 2021, the Contracting Parties to the Barcelona Convention and its Protocols are expected to adopt a decision ('the Decision of the Contracting Parties') amending Annexes I, II, III and IV and Annex VII, section A, to the Offshore Protocol.
- (4) The Decision of the Contracting Parties relates to the protection of the environment, which is a shared competence between the Union and its Member States under Article 4(2), point (e), of the Treaty. The Decision of the Contracting Parties does not fall within an area which is largely covered by Union rules concerning such protection. The Union does not intend to make use of the possibility of exercising its external competence with regard to areas covered by the Decision of the Contracting Parties in relation to which its competence has not yet been exercised internally.
- (5) It is appropriate to establish the position to be taken on the Union's behalf at the meeting of the Contracting Parties to the Barcelona Convention and its Protocols, as the Decision of the Contracting Parties concerns the adoption of amendments to Annexes I, II, III and IV and Annex VII, section A, to the Offshore Protocol that will be binding on the Union.
- (6) Since the envisaged amendments to Annexes I, II, III and IV and Annex VII, section A, to the Offshore Protocol will update requirements regarding the protection of the Mediterranean Sea, affect the Union's international commitments and ambitions and improve the protection of the environment, the Union should support the adoption of the Decision of the Contracting Parties,

⁽¹⁾ Council Decision 2013/5/EU of 17 December 2012 on the accession of the European Union to the Protocol for the Protection of the Mediterranean Sea against pollution resulting from exploration and exploitation of the continental shelf and the seabed and its subsoil (OJ L 4, 9.1.2013, p. 13).

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols shall be to support the adoption of a decision amending Annexes I, II, III and IV and Annex VII, section A, to the Protocol for the Protection of the Mediterranean Sea against Pollution Resulting from Exploration and Exploitation of the Continental Shelf and the Seabed and its Subsoil.

Article 2

In the light of developments at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols, refinement of the position referred to in Article 1 may be agreed to by the representatives of the Union, in consultation with Member States, during on-the-spot coordination meetings without a further decision of the Council.

Article 3

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

Done at Brussels, 2 December 2021.

For the Council
The President
J. VRTOVEC

COUNCIL DECISION (EU) 2022/12**of 2 December 2021**

on the position to be taken on behalf of the European Union at the 22nd meeting of the Contracting Parties to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (Barcelona Convention) and its Protocols as regards the adoption of a decision to submit a proposal to designate the Mediterranean Sea, as a whole, as an emission control area for sulphur oxides (Med SO_x ECA) pursuant to Annex VI to the International Convention for the Prevention of Pollution from Ships (MARPOL Convention)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The amended Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean ('the Barcelona Convention') was concluded by the Union by means of Council Decision 1999/802/EC ⁽¹⁾ and entered into force on 9 July 2004.
- (2) Pursuant to Article 18(2), point (vi), of the Barcelona Convention, the meeting of the Contracting Parties to the Barcelona Convention and its Protocols is to consider and undertake any action that may be required for the achievement of the purposes of the Barcelona Convention and the Protocols. Pursuant to Rule 43 of the Rules of Procedure for meetings of the Contracting Parties, unless otherwise provided by the Barcelona Convention, the Protocols or the financial terms of reference, substantive decisions are to be made by a two-thirds majority of the Contracting Parties present and voting.
- (3) During their 22nd meeting from 7 to 10 December 2021, the Contracting Parties to the Barcelona Convention and its Protocols are expected to adopt a decision ('the Decision of the Contracting Parties') to submit to the 78th session of the Marine Environment Protection Committee ('MEPC 78') of the International Maritime Organization in 2022 a proposal to designate the Mediterranean Sea, as a whole, as an emission control area for sulphur oxides (Med SO_x ECA) and to specify the date of entry into force.
- (4) The Decision of the Contracting Parties relates to the protection of the environment, which is a shared competence between the Union and its Member States under Article 4(2), point (e), of the Treaty. The Decision of the Contracting Parties does not fall within an area which is largely covered by Union rules concerning such protection. The Union does not intend to make use of the possibility of exercising its external competence with regard to areas covered by the Decision of the Contracting Parties in relation to which its competence has not yet been exercised internally.
- (5) It is appropriate to establish the position to be taken on the Union's behalf at the meeting of the Contracting Parties to the Barcelona Convention and its Protocols, as the Decision of the Contracting Parties concerns the submission of a proposal to MEPC 78, on behalf of an organisation to which the Union is a Party, to designate the Mediterranean Sea, as a whole, as an emission control area for sulphur oxides (Med SO_x ECA), and therefore constitutes an act having legal effects.
- (6) Since the purpose of the Decision of the Contracting Parties is to lead to the update of the requirements regarding the protection of the Mediterranean Sea, in line with the Union's ambition to reduce pollution in the marine environment and protect human health, the Union should support the adoption of the Decision of the Contracting Parties,

⁽¹⁾ Council Decision 1999/802/EC of 22 October 1999 on the acceptance of amendments to the Convention for the Protection of the Mediterranean Sea against Pollution and to the Protocol for the Prevention of Pollution by Dumping from Ships and Aircraft (Barcelona Convention) (OJ L 322, 14.12.1999, p. 32).

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols shall be to support the adoption of a decision to submit to the 78th session of the Marine Environment Protection Committee of the International Maritime Organization a proposal to designate the Mediterranean Sea, as a whole, as an emission control area for sulphur oxides (Med SO_x ECA) and to specify the date of entry into force.

Article 2

In the light of developments at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols, refinement of the position referred to in Article 1 may be agreed to by the representatives of the Union, in consultation with Member States, during on-the-spot coordination meetings without a further decision of the Council.

Article 3

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

Done at Brussels, 2 December 2021.

For the Council
The President
J. VRTOVEC

COUNCIL DECISION (EU) 2022/13**of 2 December 2021**

on the position to be taken on behalf of the European Union at the 22nd meeting of the Contracting Parties to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (Barcelona Convention) and its Protocols as regards the adoption of a decision to amend the Regional Plan on Marine Litter Management in the Mediterranean in the framework of Article 15 of the Protocol for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources and Activities (LBS Protocol)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The amended Protocol to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean ('the Barcelona Convention') for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources and Activities ('the LBS Protocol') was concluded by the Union by means of Council Decision 1999/801/EC ⁽¹⁾ and entered into force on 11 May 2008.
- (2) Pursuant to Article 15(1) of the LBS Protocol, the meeting of the Contracting Parties to the Barcelona Convention and its Protocols is to adopt regional action plans containing measures and timetables for their implementation.
- (3) During their 22nd meeting from 7 to 10 December 2021, the Contracting Parties to the Barcelona Convention and its Protocols are expected to adopt a decision ('the Decision of the Contracting Parties') to amend the Regional Plan on Marine Litter Management in the Mediterranean ('the Regional Plan') in the framework of Article 15 of the LBS Protocol. The Decision of the Contracting Parties will provide new definitions and will expand the scope of measures in four key areas (economic instruments, circular economy of plastics, land-based sources of marine litter and sea-based sources of marine litter).
- (4) The Decision of the Contracting Parties relates to the protection of the environment, which is a shared competence between the Union and its Member States under Article 4(2), point (e), of the Treaty. The Decision of the Contracting Parties does not fall within an area which is largely covered by Union rules concerning such protection. The Union does not intend to make use of the possibility of exercising its external competence with regard to areas covered by the Decision of the Contracting Parties in relation to which its competence has not yet been exercised internally.
- (5) It is appropriate to establish the position to be taken on the Union's behalf at the meeting of the Contracting Parties to the Barcelona Convention and its Protocols, as the Decision of the Contracting Parties concerns the adoption of amendments to the Regional Plan that will be binding on the Union pursuant to Article 15(3) of the LBS Protocol.
- (6) Since the envisaged amendments to the Regional Plan are in line with the Union's ambition to reduce pollution and improve the protection of the environment, the Union should support the adoption of the Decision of the Contracting Parties,

⁽¹⁾ Council Decision 1999/801/EC of 22 October 1999 on accepting the amendments to the Protocol for the protection of the Mediterranean Sea against pollution from land-based sources (Barcelona Convention) (OJ L 322, 14.12.1999, p. 18).

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols shall be to support the adoption of a decision to amend the Regional Plan on Marine Litter Management in the Mediterranean in the framework of Article 15 of the Protocol for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources and Activities.

Article 2

In the light of developments at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols, refinement of the position referred to in Article 1 may be agreed to by the representatives of the Union, in consultation with Member States, during on-the-spot coordination meetings without a further decision of the Council.

Article 3

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

Done at Brussels, 2 December 2021.

For the Council
The President
J. VRTOVEC

COUNCIL DECISION (EU) 2022/14
of 2 December 2021

on the position to be taken on behalf of the European Union at the 22nd meeting of the Contracting Parties to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (Barcelona Convention) and its Protocols as regards the adoption of a decision to adopt Regional Plans on Urban Wastewater Treatment and Sewage Sludge Management in the framework of Article 15 of the Protocol for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources and Activities (LBS Protocol)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The amended Protocol to the Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean ('the Barcelona Convention') for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources and Activities ('the LBS Protocol') was concluded by the Union by means of Council Decision 1999/801/EC ⁽¹⁾ and entered into force on 11 May 2008.
- (2) Pursuant to Article 15(1) of the LBS Protocol, the meeting of the Contracting Parties to the Barcelona Convention and its Protocols is to adopt regional action plans containing measures and timetables for their implementation.
- (3) During their 22nd meeting from 7 to 10 December 2021, the Contracting Parties to the Barcelona Convention and its Protocols are expected to adopt a decision ('the Decision of the Contracting Parties') adopting Regional Plans on Urban Wastewater Treatment and Sewage Sludge Management ('the Regional Plans') in the framework of Article 15 of the LBS Protocol.
- (4) The Decision of the Contracting Parties relates to the protection of the environment, which is a shared competence between the Union and its Member States under Article 4(2), point (e), of the Treaty. The Decision of the Contracting Parties does not fall within an area which is largely covered by Union rules concerning such protection. The Union does not intend to make use of the possibility of exercising its external competence with regard to areas covered by the Decision of the Contracting Parties in relation to which its competence has not yet been exercised internally.
- (5) It is appropriate to establish the position to be taken on the Union's behalf at the meeting of the Contracting Parties to the Barcelona Convention and its Protocols, as the Decision of the Contracting Parties concerns the adoption of the Regional Plans that will be binding on the Union pursuant to Article 15(3) of the LBS Protocol.
- (6) Since the purpose of the Regional Plans is to update requirements regarding the protection of the Mediterranean Sea, modify the Union's international commitments and ambitions and improve the protection of the environment, the Union should support the adoption of the Decision of the Contracting Parties,

⁽¹⁾ Council Decision 1999/801/EC of 22 October 1999 on accepting the amendments to the Protocol for the protection of the Mediterranean Sea against pollution from land-based sources (Barcelona Convention) (OJ L 322, 14.12.1999, p. 18).

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols shall be to support the adoption of a decision adopting Regional Plans on urban wastewater treatment and sewage sludge management in the framework of Article 15 of the Protocol for the Protection of the Mediterranean Sea against Pollution from Land-Based Sources and Activities.

Article 2

In the light of developments at the 22nd meeting of the Contracting Parties to the Barcelona Convention and its Protocols, refinement of the position referred to in Article 1 may be agreed to by the representatives of the Union, in consultation with Member States, during on-the-spot coordination meetings without a further decision of the Council.

Article 3

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

Done at Brussels, 2 December 2021.

For the Council
The President
J. VRTOVEC

COMMISSION IMPLEMENTING DECISION (EU) 2022/15

of 6 January 2022

amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer and requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ⁽¹⁾, and in particular Article 10(6) thereof,

Whereas:

- (1) In accordance with Article 8(1) of Regulation (EU) 2017/746 of the European Parliament and of the Council ⁽²⁾, devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, are to be presumed to be in conformity with the requirements of that Regulation covered by those standards or parts thereof.
- (2) Regulation (EU) 2017/746 will replace Directive 98/79/EC of the European Parliament and of the Council ⁽³⁾ from 26 May 2022.
- (3) By Implementing Decision C(2021) 2406 ⁽⁴⁾, the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) for the revision of existing harmonised standards on *in vitro* diagnostic medical devices developed in support of Directive 98/79/EC and the drafting of new harmonised standards in support of Regulation (EU) 2017/746.
- (4) On the basis of the request set out in Implementing Decision C(2021) 2406, CEN and Cenelec revised the existing harmonised standards EN ISO 11737-1:2018, EN ISO 13408-6:2011, EN ISO 13485:2016, EN ISO 15223-1:2016 and EN ISO 17511:2003, in order to take into account the latest technical and scientific progress and to adapt them to the requirements of Regulation (EU) 2017/746. This resulted in the adoption of the revised harmonised standards EN ISO 13408-6:2021 on aseptic processing of health care products, EN ISO 15223-1:2021 on symbols to be used with information to be supplied by the manufacturer and EN ISO 17511:2021 on requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples and of amendment EN ISO 11737-1:2018/A1:2021 to harmonised standard EN ISO 11737-1:2018 on sterilization of health care products and amendment EN ISO 13485:2016/A11:2021 to harmonised standard EN ISO 13485:2016 on quality management systems.

⁽¹⁾ OJ L 316, 14.11.2012, p. 12.

⁽²⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

⁽³⁾ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

⁽⁴⁾ Commission Implementing Decision C(2021) 2406 of 14 April 2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council.

- (5) The Commission together with CEN and Cenelec has assessed whether the harmonised standards revised by CEN and Cenelec comply with the request set out in Implementing Decision C(2021) 2406.
- (6) The harmonised standards EN ISO 13408-6:2021, EN ISO 15223-1:2021 and EN ISO 17511:2021 and the amendments EN ISO 11737-1:2018/A1:2021 and EN ISO 13485:2016/A11:2021 satisfy the requirements which they aim to cover and which are set out in Regulation (EU) 2017/746. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.
- (7) The Annex to Commission Implementing Decision (EU) 2021/1195 ^(*) lists the references of harmonised standards drafted in support of Regulation (EU) 2017/746. In order to ensure that the references of harmonised standards drafted in support of Regulation (EU) 2017/746 are listed in one act, the references of standards EN ISO 13408-6:2021, EN ISO 15223-1:2021 and EN ISO 17511:2021 and the amendments EN ISO 11737-1:2018/A1:2021 and EN ISO 13485:2016/A11:2021 should be included in that Implementing Decision.
- (8) Implementing Decision (EU) 2021/1195 should therefore be amended accordingly.
- (9) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2021/1195 is amended in accordance with 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, 6 January 2022.

For the Commission
The President
Ursula VON DER LEYEN

^(*) Commission Implementing Decision (EU) 2021/1195 of 19 July 2021 on the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (OJ L 258, 20.7.2021, p. 50).

ANNEX

In the Annex to Implementing Decision (EU) 2021/1195, the following entries are added:

No	Reference of the standard
5.	EN ISO 11737-1:2018 Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018) EN ISO 11737-1:2018/A1:2021
6.	EN ISO 13408-6:2021 Aseptic processing of health care products – Part 6: Isolator systems (ISO 13408-6:2021)
7.	EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/A11:2021
8.	EN ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements (ISO 15223-1:2021)
9.	EN ISO 17511:2021 <i>In vitro</i> diagnostic medical devices – Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020).

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