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Price: EUR 3

⁽¹⁾ Text with EEA relevance

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I

(Legislative acts)

REGULATIONS

REGULATION (EU) No 1257/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 20 November 2013****on ship recycling and amending Regulation (EC) No 1013/2006 and Directive 2009/16/EC****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

(1) Ships which constitute waste and which are subject to a transboundary movement for recycling are regulated by the Basel Convention of 22 March 1989 on the Control of the Transboundary Movements of Hazardous Wastes and their Disposal ('the Basel Convention') and Regulation (EC) No 1013/2006 of the European Parliament and of the Council ⁽³⁾. Regulation (EC) No 1013/2006 implements the Basel Convention as well as an amendment ⁽⁴⁾ to that Convention adopted in 1995, which has not yet entered into force at international level, and which establishes a ban on exports of hazardous waste to countries that are not members of the Organisation

for Economic Cooperation and Development (OECD). Such ships are generally classified as hazardous waste and prohibited from being exported from the Union for recycling in facilities in countries that are not members of the OECD.

(2) The mechanisms for monitoring the application of, and enforcing the current Union and international law are not adapted to the specificities of ships and international shipping. Efforts involving inter-agency cooperation between the International Labour Organisation (ILO), the International Maritime Organisation (IMO) and the Secretariat of the Basel Convention have been successful in reaching agreement on the introduction of mandatory requirements, at global level, aimed at ensuring an efficient and effective solution to unsafe and unsound ship recycling practices in the form of the Hong Kong International Convention for the Safe and Environmentally Sound Recycling of Ships ('the Hong Kong Convention').

(3) Current ship recycling capacity in OECD countries which is legally accessible to ships flying the flag of a Member State is insufficient. Current safe and environmentally sound ship recycling capacity in countries which are not members of the OECD is sufficient to treat all ships flying the flag of a Member State and is expected to expand further by 2015 as the results of actions taken by recycling countries to meet the requirements of the Hong Kong Convention.

(4) The Hong Kong Convention was adopted on 15 May 2009 under the auspices of the International Maritime Organization. The Hong Kong Convention will enter into force only 24 months after the date of ratification by at least 15 states representing a combined merchant fleet of at least 40 per cent of the gross tonnage of the world's merchant shipping and whose combined maximum annual ship recycling volume during the preceding 10 years constitutes not less than three per cent of the gross tonnage of the combined merchant shipping of the same states. That Convention covers the design, the

⁽¹⁾ OJ C 299, 4.10.2012, p. 158.

⁽²⁾ Position of the European Parliament of 22 October 2013 (not yet published in the Official Journal) and decision of the Council of 15 November 2013.

⁽³⁾ Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste (OJ L 190, 12.7.2006, p. 1).

⁽⁴⁾ Amendment to the Basel Convention ('Ban amendment') adopted by Decision III/1 of the Parties to the Basel Convention.

construction, the operation and the preparation of ships with a view to facilitating safe and environmentally sound recycling without compromising ship safety and operational efficiency. It also covers the operation of ship recycling facilities in a safe and environmentally sound manner, and the establishment of an appropriate enforcement mechanism for ship recycling.

- (5) This Regulation is aimed at facilitating early ratification of the Hong Kong Convention both within the Union and in third countries by applying proportionate controls to ships and ship recycling facilities on the basis of that Convention.
- (6) The Hong Kong Convention provides explicitly for its Parties to take more stringent measures consistent with international law, with respect to the safe and environmentally sound recycling of ships, in order to prevent, reduce or minimise any adverse effects on human health and the environment. Taking that into account, this Regulation should provide protection from the possible adverse effects of hazardous materials on board all ships calling at a port or anchorage of a Member State while ensuring compliance with the provisions applicable to those materials under international law. In order to ensure the monitoring of compliance with the requirements relating to hazardous materials under this Regulation, Member States should apply national provisions to implement Directive 2009/16/EC of the European Parliament and of the Council⁽¹⁾. Currently, port State control inspectors are tasked with the inspection of certification and with active testing for hazardous materials, including asbestos, under the International Convention for the Safety of Life at Sea ('SOLAS'). The Paris Memorandum of Understanding on Port State Control provides a harmonised approach for those activities.
- (7) The purpose of this Regulation is also to reduce disparities between operators in the Union, in OECD countries and in relevant third countries in terms of health and safety at the workplace and environmental standards and to direct ships flying the flag of a Member State to ship recycling facilities that practice safe and environmentally sound methods of dismantling ships instead of directing them to substandard sites as is currently the practice. The competitiveness of safe and environmentally sound recycling and treatment of ships in ship recycling facilities located in a Member State would thereby also be increased. The establishment of a European List of ship recycling facilities ('the European List') fulfilling the requirements set out in this Regulation would contribute to those objectives as well as to better enforcement by facilitating the control of ships going for recycling by the Member State whose flag the ship is flying. Those requirements for ship recycling facilities should be based on the requirements of the Hong Kong Convention. In this regard, ship

recycling facilities approved in accordance with this Regulation should meet the necessary requirements to ensure protection of the environment, the health and safety of workers and the environmentally sound management of the waste recovered from recycled ships. For ship recycling facilities located in a third country, the requirements should achieve a high level of protection of human health and the environment that is broadly equivalent to that in the Union. Ship recycling facilities which do not meet those minimum requirements should therefore not be included in the European List.

- (8) The principle of equality in Union law should be applied and its application monitored, in particular when establishing and updating the European List in respect of ship recycling facilities located in a Member State and ship recycling facilities located in a third country fulfilling the requirements set out in this Regulation.
- (9) Member States are encouraged to adopt appropriate measures to ensure that ships excluded from the scope of this Regulation act in a manner that is consistent with this Regulation, in so far as is reasonable and practicable.
- (10) In order to avoid duplication, it is necessary to exclude ships flying the flag of a Member State falling under the scope of this Regulation from the scope of application of Regulation (EC) No 1013/2006 and of Directive 2008/98/EC of the European Parliament and of the Council⁽²⁾ respectively. Regulation (EC) No 1013/2006 applies to shipments of waste from the Union, subject to exclusions for certain categories of waste where an alternative regime applies. This Regulation subjects ships within its scope to controls throughout their life-cycle and aims to secure recycling of those ships in an environmentally sound manner. It is therefore appropriate to specify that a ship subject to the alternative control regime throughout its life-cycle under this Regulation should not be subject to Regulation (EC) No 1013/2006. Ships neither covered by the scope of the Hong Kong Convention nor by this Regulation, and any waste on board of a ship other than operationally generated waste, should continue to be subject to Regulation (EC) No 1013/2006 and to Directives 2008/98/EC and 2008/99/EC of the European Parliament and of the Council⁽³⁾, respectively.
- (11) It is also acknowledged that ships continue to be subject to other international conventions to ensure their safe operation at sea during the operational part of their life-cycle and, although they can exercise certain navigational rights and freedoms, ships are required to

⁽¹⁾ Directive 2009/16/EC of the European Parliament and of the Council of 23 April 2009 on port State control (OJ L 131, 28.5.2009, p. 57).

⁽²⁾ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).

⁽³⁾ Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law (OJ L 328, 6.12.2008, p. 28).

provide prior notice of entry into ports. Member States should be able to choose to apply further controls in accordance with other international treaties. Additional transit controls are therefore not considered necessary under this Regulation.

- (12) When interpreting the requirements of this Regulation, consideration should be given to the guidelines developed by the IMO ('IMO guidelines') to support the Hong Kong Convention.
- (13) For the purposes of this Regulation, the term 'recycling' should not have the same meaning as defined in Directive 2008/98/EC. This Regulation should therefore introduce a specific definition for the term 'ship recycling'.
- (14) Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹⁾ implements at Union level the Globally Harmonised System for the classification and labelling of chemicals. That Regulation, together with Council Directive 67/548/EEC ⁽²⁾ and Directive 1999/45/EC of the European Parliament and of the Council ⁽³⁾, provides useful guidance in determining what constitutes a hazardous material.
- (15) Keeping an inventory of hazardous materials on board a ship throughout its life-cycle is a key requirement laid down in the Hong Kong Convention and in this Regulation. In accordance with Regulation 8(2) of the Hong Kong Convention, a ship destined to be recycled should minimise the amounts of operationally generated waste in the period prior to entering the ship recycling facility. If the operationally generated waste is intended for delivery with the ship to a ship recycling facility, the approximate quantities and locations of that waste should be listed in Part II of the inventory.
- (16) Member States should take measures to prevent circumvention of ship recycling rules and to enhance transparency of ship recycling. As provided for in the Hong Kong Convention, Member States should report information concerning ships to which an inventory certificate has been issued, ships for which a statement of completion has been received and information regarding illegal ship recycling and follow-up actions that they have undertaken.
- (17) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those penalties are applied so as to prevent

circumvention of ship recycling rules. The penalties, which may be of a civil or administrative nature, should be effective, proportionate and dissuasive.

- (18) In accordance with the case-law of the Court of Justice, the courts of the Member States are required to interpret, to the fullest extent possible, the procedural rules relating to the conditions to be met in order to bring administrative or judicial proceedings in accordance with the objectives of Article 9(3) of the Aarhus Convention.
- (19) In the interest of protecting human health and the environment and having regard to the 'polluter pays' principle, the Commission should assess the feasibility of establishing a financial mechanism applicable to all ships calling at a port or anchorage of a Member State, irrespective of the flag they are flying, to generate resources that would facilitate the environmentally sound recycling and treatment of ships without creating an incentive to out-flag.
- (20) In order to take into account developments regarding the Hong Kong Convention, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the updating of Annexes I and II to this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (21) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽⁴⁾.
- (22) Since the objective of this Regulation, namely to prevent, reduce or eliminate adverse effects on human health and the environment caused by the recycling, operation and maintenance of ships flying the flag of a Member State, cannot be sufficiently achieved by the Member States due to the international character of shipping and ship recycling, but can rather by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

⁽¹⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽²⁾ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 196, 16.8.1967, p. 1).

⁽³⁾ Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1).

⁽⁴⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

HAVE ADOPTED THIS REGULATION:

TITLE I

SUBJECT-MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and purpose

The purpose of this Regulation is to prevent, reduce, minimise and, to the extent practicable, eliminate accidents, injuries and other adverse effects on human health and the environment caused by ship recycling. The purpose of this Regulation is to enhance safety, the protection of human health and of the Union marine environment throughout a ship's life-cycle, in particular to ensure that hazardous waste from such ship recycling is subject to environmentally sound management.

This Regulation also lays down rules to ensure the proper management of hazardous materials on ships.

This Regulation also aims to facilitate the ratification of the Hong Kong International Convention for the Safe and Environmentally Sound Recycling of Ships, 2009 ('the Hong Kong Convention').

Article 2

Scope

1. This Regulation, with the exception of Article 12, shall apply to ships flying the flag of a Member State.

Article 12 shall apply to ships flying the flag of a third country calling at a port or anchorage of a Member State.

2. This Regulation shall not apply to:

- (a) any warships, naval auxiliary, or other ships owned or operated by a state and used, for the time being, only on government non-commercial service;
- (b) ships of less than 500 gross tonnage (GT);
- (c) ships operating throughout their life only in waters subject to the sovereignty or jurisdiction of the Member State whose flag the ship is flying.

Article 3

Definitions

1. For the purposes of this Regulation, the following definitions apply:

- (1) 'ship' means a vessel of any type whatsoever operating or having operated in the marine environment, and includes submersibles, floating craft, floating platforms, self-elevating platforms, Floating Storage Units (FSUs), and Floating Production Storage and Offloading Units (FPSOs), as well as a vessel stripped of equipment or being towed;
- (2) 'new ship' means a ship for which either:
 - (a) the building contract is placed on or after the date of application of this Regulation;
 - (b) in the absence of a building contract, the keel is laid or the ship is at a similar stage of construction six months after the date of application of this Regulation or thereafter; or
 - (c) the delivery takes place thirty months after the date of application of this Regulation or thereafter;
- (3) 'tanker' means an oil tanker as defined in Annex I to the Convention for the Prevention of Pollution from Ships ('MARPOL Convention') or a Noxious Liquid Substances (NLS) tanker as defined in Annex II to that Convention;
- (4) 'hazardous material' means any material or substance which is liable to create hazards to human health and/or the environment;
- (5) 'operationally generated waste' means waste water and residues generated by the normal operation of ships subject to the requirements of the MARPOL Convention;
- (6) 'ship recycling' means the activity of complete or partial dismantling of a ship at a ship recycling facility in order to recover components and materials for reprocessing, for preparation for re-use or for re-use, whilst ensuring the management of hazardous and other materials, and includes associated operations such as storage and treatment of components and materials on site, but not their further processing or disposal in separate facilities;
- (7) 'ship recycling facility' means a defined area that is a yard or facility located in a Member State or in a third country and used for the recycling of ships;
- (8) 'ship recycling company' means, the owner of the ship recycling facility or any other organisation or person who has assumed the responsibility for the operation of the ship recycling activity from the owner of the ship recycling facility;

- (9) 'administration' means a governmental authority designated by a Member State as being responsible for duties related to ships flying its flag or to ships operating under its authority;
- (10) 'recognised organisation' means an organisation recognised in accordance with Regulation (EC) No 391/2009 of the European Parliament and of the Council ⁽¹⁾;
- (11) 'competent authority' means a governmental authority or authorities designated by a Member State or a third country as responsible for ship recycling facilities, within a specified geographical area or an area of expertise, relating to all operations within the jurisdiction of that state;
- (12) 'gross tonnage' means the gross tonnage (GT) calculated in accordance with the tonnage measurement regulations contained in Annex I to the International Convention on Tonnage Measurement of Ships, 1969, or any successor convention;
- (13) 'competent person' means a person with suitable qualifications, training, and sufficient knowledge, experience and skill, for the performance of the specific work;
- (14) 'ship owner' means the natural or legal person registered as the owner of the ship, including the natural or legal person owning the ship for a limited period pending its sale or handover to a ship recycling facility, or, in the absence of registration, the natural or legal person owning the ship or any other organisation or person, such as the manager or the bareboat charterer, who has assumed the responsibility for operation of the ship from the owner of the ship, and the legal person operating a state-owned ship;
- (15) 'new installation' means the installation of systems, equipment, insulation or other material on a ship after the date of application of this Regulation;
- (16) 'ship recycling plan' means a plan developed by the operator of the ship recycling facility for each specific ship to be recycled under its responsibility taking into account the relevant IMO guidelines and resolutions;
- (17) 'ship recycling facility plan' means a plan prepared by the operator of the ship recycling facility and adopted by the board or the appropriate governing body of the ship recycling company that describes the operational processes and procedures involved in ship recycling at the ship recycling facility and that covers in particular workers' safety and training, protection of human health and the environment, roles and responsibilities of personnel, emergency preparedness and response, and systems for monitoring, reporting and record-keeping, taking into account the relevant IMO guidelines and resolutions;
- (18) 'safe-for-entry' means a space that meets all of the following criteria:
- (a) the oxygen content of the atmosphere and the concentration of flammable vapours are within safe limits;
 - (b) any toxic materials in the atmosphere are within permissible concentrations;
 - (c) any residues or materials associated with the work authorised by the competent person will not produce uncontrolled release of toxic materials or an unsafe concentration of flammable vapours under existing atmospheric conditions while maintained as directed;
- (19) 'safe-for-hot work' means a space in which all of the following criteria are met:
- (a) safe, non-explosive conditions, including gas-free status, exist for the use of electric arc or gas welding equipment, cutting or burning equipment or other forms of naked flame, as well as heating, grinding, or spark-generating operations;
 - (b) the safe-for-entry criteria set out in point 18 are met;
 - (c) existing atmospheric conditions do not change as a result of the hot work;
 - (d) all adjacent spaces have been cleaned, rendered inert or treated sufficiently to prevent the start or spread of fire;
- (20) 'statement of completion' means a confirmatory statement issued by the operator of the ship recycling facility that the ship recycling has been completed in accordance with this Regulation;
- (21) 'inventory certificate' means a ship-specific certificate that is issued to ships flying the flag of a Member State in accordance with Article 9 and that is supplemented by an inventory of hazardous materials in accordance with Article 5;
- (22) 'ready for recycling certificate' means a ship-specific certificate that is issued to ships flying the flag of a Member State in accordance with Article 9(9) and that is supplemented by an inventory of hazardous materials in accordance with Article 5(7) and the approved ship recycling plan in accordance with Article 7;

⁽¹⁾ Regulation (EC) No 391/2009 of the European Parliament and of the Council of 23 April 2009 on common rules and standards for ship inspection and survey organisations (OJ L 131, 28.5.2009, p. 11).

(23) 'statement of compliance' means a ship-specific certificate that is issued to ships flying the flag of a third country and that is supplemented by an inventory of hazardous materials in accordance with Article 12;

(24) 'light displacement tonnes (LDT)' means the weight of a ship in tonnes without cargo, fuel, lubricating oil in storage tanks, ballast water, fresh water, feedwater, consumable stores, passengers and crew and their effects and it is the sum of the weight of the hull, structure, machinery, equipment and fittings of the ship.

2. For the purposes of Article 7(2)(d) and Articles 13, 15 and 16,

(a) 'waste', 'hazardous waste', 'treatment' and 'waste management' have the same meaning as in Article 3 of Directive 2008/98/EC;

(b) 'site inspection' means an inspection of the ship recycling facility assessing whether the conditions on site are consistent with those described in any relevant documentation provided;

(c) 'worker' means any person who performs work, either regularly or temporarily, in the context of an employment relationship, including the personnel working for contractors and subcontractors;

(d) 'environmentally sound management' means taking all practicable steps to ensure that waste and hazardous materials are managed in a manner which protects human health and the environment against the adverse effects which may result from such materials and waste.

3. For the purposes of point 13 of paragraph 1, a competent person may be a trained worker or a managerial employee capable of recognising and evaluating occupational hazards, risks, and employee exposure to potentially hazardous materials or unsafe conditions in a ship recycling facility, and who is capable of specifying the necessary protection and precautions to be taken to eliminate or reduce those hazards, risks or that exposure.

Without prejudice to Directive 2005/36/EC of the European Parliament and of the Council ⁽¹⁾, the competent authority may define appropriate criteria for the designation of such persons and may determine the duties to be assigned to them.

TITLE II

SHIPS

Article 4

Control of hazardous materials

The installation or use of hazardous materials referred to in Annex I on ships shall be prohibited or restricted as specified

in Annex I, without prejudice to other requirements of relevant Union law which may require further measures.

Article 5

Inventory of hazardous materials

1. Each new ship shall have on board an inventory of hazardous materials, which shall identify at least the hazardous materials referred to in Annex II and contained in the structure or equipment of the ship, their location and approximate quantities.

2. Subject to point (b) of Article 32(2), existing ships shall comply, as far as practicable, with paragraph 1.

In the case of ships going for recycling, they shall comply, as far as practicable, with paragraph 1 of this Article from the date of the publication of the European List of ship recycling facilities ('the European List') as set out in Article 16(2).

Subject to point (b) of Article 32(2), when the inventory of hazardous materials is developed it shall identify, at least, the hazardous materials listed in Annex I.

3. The inventory of hazardous materials shall:

(a) be specific to each ship;

(b) provide evidence that the ship complies with the prohibition or restrictions on installing or using hazardous materials in accordance with Article 4;

(c) be compiled taking into account the relevant IMO guidelines;

(d) be verified either by the administration or a recognised organisation authorised by it.

4. In addition to paragraph 3, for existing ships a plan shall be prepared describing the visual or sampling check by which the inventory of hazardous materials is developed and taking into account the relevant IMO guidelines.

5. The inventory of hazardous materials shall consist of three parts:

(a) a list of hazardous materials referred to in Annexes I and II, in accordance with the provisions of paragraphs 1 and 2 of this Article, and contained in the structure or equipment of the ship, with an indication of their location and approximate quantities (Part I);

⁽¹⁾ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (OJ L 255, 30.9.2005, p. 22).

(b) a list of the operationally generated waste present on board the ship (Part II);

(c) a list of the stores present on board the ship (Part III).

6. Part I of the inventory of hazardous materials shall be properly maintained and updated throughout the operational life of the ship, reflecting new installations containing any hazardous materials referred to in Annex II and relevant changes in the structure and equipment of the ship.

7. Prior to recycling, and taking into account the relevant IMO guidelines, the inventory of hazardous materials shall, in addition to the properly maintained and updated Part I, incorporate Part II for operationally generated waste and Part III for stores, and be verified by the administration or a recognised organisation authorised by it.

8. The Commission shall be empowered to adopt delegated acts in accordance with Article 24 concerning the updating of the list of items for the inventory of hazardous materials in Annexes I and II to ensure that the lists include at least the substances listed in Appendices I and II of the Hong Kong Convention.

The Commission shall adopt a separate delegated act in respect of each substance to be added or deleted from Annexes I or II.

Article 6

General requirements for ship owners

1. When preparing to send a ship for recycling, ship owners shall:

(a) provide the operator of the ship recycling facility with all ship-relevant information, necessary for the development of the ship recycling plan set out in Article 7;

(b) notify in writing the relevant administration, within a timeframe to be determined by that administration, of the intention to recycle the ship in a specified ship recycling facility or facilities. The notification shall include at least:

(i) the inventory of hazardous materials; and

(ii) all ship-relevant information provided under point (a).

2. Ship owners shall ensure that ships destined to be recycled:

(a) are only recycled at ship recycling facilities that are included in the European List;

(b) conduct operations in the period prior to entering the ship recycling facility in such a way as to minimise the amount

of cargo residues, remaining fuel oil, and ship generated waste remaining on board;

(c) hold a ready for recycling certificate issued by the administration or a recognised organisation authorised by it prior to any recycling of the ship and after the receipt of the ship recycling plan approved in accordance with Article 7(3).

3. Ship owners shall ensure that tankers arrive at the ship recycling facility with cargo tanks and pump rooms in a condition ready for certification as safe-for-hot work.

4. Ship owners shall provide the operator of the ship recycling facility with a copy of the ready for recycling certificate issued in accordance with Article 9.

5. Ship owners shall be responsible for the ship and shall make arrangements to maintain that ship in compliance with the requirements of the administration of the Member State whose flag the ship is flying up until such time as the operator of the ship recycling facility accepts responsibility for that ship. The operator of the ship recycling facility may decline to accept the ship for recycling if the condition of the ship does not correspond substantially with the particulars of the inventory certificate, including where Part I of the inventory of hazardous materials has not been properly maintained and updated, reflecting changes in the ship's structure and equipment. In such circumstances, the ship owner shall retain responsibility for that ship and shall inform the administration thereof without delay.

Article 7

Ship recycling plan

1. A ship-specific ship recycling plan shall be developed prior to any recycling of a ship. The ship recycling plan shall address any ship-specific considerations that are not covered in the ship recycling facility plan or that require special procedures.

2. The ship recycling plan shall:

(a) be developed by the operator of the ship recycling facility in accordance with the relevant provisions of the Hong Kong Convention and taking into account the relevant IMO guidelines and the ship-relevant information provided by the ship owner in accordance with Article 6(1)(a) so that its contents are consistent with the information contained in the inventory of hazardous materials;

(b) clarify whether and to what extent any preparatory work, such as pre-treatment, identification of potential hazards and removal of stores, is to take place at a location other than the ship recycling facility identified in the ship recycling plan. The ship recycling plan should include the location where the ship will be placed during recycling operations and a concise plan for the arrival and safe placement of the specific ship to be recycled;

- (c) include information concerning the establishment, maintenance and monitoring of the safe-for-entry and safe-for-hot work conditions for the specific ship, taking into account features such as its structure, configuration and previous cargo, and other necessary information on how the ship recycling plan is to be implemented;
- (d) include information on the type and amount of hazardous materials and of waste to be generated by the recycling of the specific ship, including the materials and the waste identified in the inventory of hazardous materials, and on how they will be managed and stored in the ship recycling facility as well as in subsequent facilities; and
- (e) be prepared separately, in principle, for each ship recycling facility involved where more than one ship recycling facility is to be used, and identify the order of use and the authorised activities that will occur at those facilities.

3. The ship recycling plan shall be tacitly or explicitly approved by the competent authority in accordance with the requirements of the state where the ship recycling facility is located, where applicable.

Explicit approval shall be given when the competent authority sends a written notification of its decision on the ship recycling plan to the operator of the ship recycling facility, the ship owner and the administration.

Tacit approval shall be deemed given, if no written objection to the ship recycling plan is communicated by the competent authority to the operator of the ship recycling facility, the ship owner and the administration within a review period laid down in accordance with the requirements of the state where the ship recycling facility is located, where applicable, and notified in accordance with Article 15(2)(b).

4. Member States may require their administration to send to the competent authority of the state where the ship recycling facility is located the information provided by the ship owner pursuant to Article 6(1)(b) and the following details:

- (i) the date on which the ship was registered within the State whose flag it flies;
- (ii) the ship's identification number (IMO number);
- (iii) the hull number on new-building delivery;
- (iv) the name and type of the ship;
- (v) the port at which the ship is registered;
- (vi) the name and address of the ship owner as well as the IMO registered owner identification number;
- (vii) the name and address of the company;

(viii) the name of any classification societies with which the ship is classed;

(ix) the ship's main particulars (Length overall (LOA), Breadth (Moulded), Depth (Moulded), LDT, Gross and Net tonnage, and engine type and rating).

Article 8

Surveys

1. Surveys of ships shall be carried out by officers of the administration, or of a recognised organisation authorised by it, taking into account the relevant IMO guidelines.

2. Where the administration uses recognised organisations to conduct surveys, as described in paragraph 1, it shall, as a minimum, empower such recognised organisations to:

- require a ship that they survey to comply with this Regulation; and
- carry out surveys if requested by the appropriate authorities of a Member State.

3. Ships shall be subject to the following surveys:

- (a) an initial survey;
- (b) a renewal survey;
- (c) an additional survey;
- (d) a final survey.

4. The initial survey of a new ship shall be conducted before the ship is put in service, or before the inventory certificate is issued. For existing ships, an initial survey shall be conducted by 31 December 2020. The survey shall verify that Part I of the inventory of hazardous materials complies with the requirements of this Regulation.

5. The renewal survey shall be conducted at intervals specified by the administration, which shall not exceed five years. The renewal survey shall verify that Part I of the inventory of hazardous materials complies with the requirements of this Regulation.

6. The additional survey, either general or partial depending on the circumstances, shall be conducted if requested by the ship owner after a change, replacement or significant repair of the structure, equipment, systems, fittings, arrangements and material, which has an impact on the inventory of hazardous materials. The survey shall be such as to ensure that any change, replacement, or significant repair has been made in a manner that ensures that the ship continues to comply with the requirements of this Regulation, and that Part I of the inventory of hazardous materials is amended as necessary.

7. The final survey shall be conducted prior to the ship being taken out of service and before the recycling of the ship has started.

That survey shall verify that:

- (a) the inventory of hazardous materials complies with the requirements of Article 5;
- (b) the ship recycling plan properly reflects the information contained in the inventory of hazardous materials and complies with the requirements of Article 7;
- (c) the ship recycling facility where the ship is to be recycled is included in the European List.

8. For existing ships intended for ship recycling, the initial survey and the final survey may be conducted at the same time.

Article 9

Issuance and endorsement of certificates

1. After successful completion of an initial or renewal survey, the administration or a recognised organisation authorised by it shall issue an inventory certificate. That certificate shall be supplemented by Part I of the inventory of hazardous materials, referred to in Article 5(5)(a).

Where the initial survey and the final survey are conducted at the same time as provided for in Article 8(8), only the ready for recycling certificate referred to in paragraph 9 of this Article shall be issued.

The Commission shall adopt implementing acts to establish the format of the inventory certificate to ensure it is consistent with Appendix 3 to the Hong Kong Convention. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25 of this Regulation.

2. An inventory certificate shall be endorsed at the request of the ship owner either by the administration or by a recognised organisation authorised by it after successful completion of an additional survey conducted in accordance with Article 8(6).

3. Subject to paragraph 4, the administration or recognised organisation authorised by it shall issue or endorse, as appropriate, an inventory certificate, where the renewal survey is successfully completed:

- (a) in the three month period before the expiry date of the existing inventory certificate, and the new certificate shall be valid from the date of completion of the renewal survey to a date not exceeding five years from the date of expiry of the existing one;

- (b) after the expiry date of the existing inventory certificate, and the new certificate shall be valid from the date of completion of the renewal survey to a date not exceeding five years from the date of expiry of the existing one;

- (c) more than three months before the expiry date of the existing inventory certificate, and the new certificate shall be valid from the date of completion of the renewal survey to a date not exceeding five years from the date of completion of the renewal survey.

4. Where a renewal survey has been successfully completed and a new inventory certificate cannot be issued or placed on board before the expiry date of the existing certificate, the administration or recognised organisation authorised by it shall endorse the existing certificate and such a certificate shall be accepted as valid for a further period which shall not exceed five months from the date of expiry.

5. In case of an inventory certificate issued for a period of less than five years, the administration or the recognised organisation authorised by it may extend the validity of the existing certificate for a further period which shall not exceed five years.

6. In special circumstances as determined by the administration, a new inventory certificate need not be dated from the date of expiry of the existing certificate as required by points (a) and (b) of paragraph 3 and paragraphs 7 and 8. In those circumstances, the new certificate shall be valid for a period not exceeding five years from the date of completion of the renewal survey.

7. Where a ship is not at the port or anchorage where it is to be surveyed when the inventory certificate expires, the administration may, if it is proper to do so, extend the period of validity of the inventory certificate for a period not exceeding three months to enable the ship to complete its voyage to the port in which it is to be surveyed. Any such extension granted shall be conditional on the survey being completed at that port before the ship leaves. A ship to which an extension is granted shall not, on its arrival in the port in which it is to be surveyed, be entitled, by virtue of such extension, to leave the port without having a new certificate. When the renewal survey is completed, the new inventory certificate shall be valid for a period not exceeding five years from the date of expiry of the existing certificate before the extension was granted.

8. An inventory certificate for a ship engaged on short voyages and which has not been extended under the conditions referred to in paragraph 7 may be extended by the administration for a period of grace of up to one month from its expiry. When the renewal survey is completed, the new inventory certificate shall be valid for a period not exceeding five years from the date of expiry of the existing certificate before the extension was granted.

9. After successful completion of a final survey in accordance with Article 8(7), the administration or a recognised organisation authorised by it shall issue a ready for recycling certificate. That certificate shall be supplemented by the inventory of hazardous materials and the ship recycling plan.

The Commission shall adopt implementing acts to establish the format of the ready for recycling certificate to ensure it is consistent with Appendix 4 to the Hong Kong Convention. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25 of this Regulation. A ready for recycling certificate issued after a final survey in accordance with the first subparagraph of this paragraph shall be accepted by the other Member States and regarded for the purposes of this Regulation as having the same validity as a ready for recycling certificate issued by them.

Article 10

Duration and validity of certificates

1. Subject to Article 9, an inventory certificate shall be issued for a period specified by the administration, which shall not exceed five years.

2. An inventory certificate issued or endorsed under Article 9 shall cease to be valid in any of the following cases:

(a) if the condition of the ship does not correspond substantially with the particulars of that inventory certificate, including where Part I of the inventory of hazardous materials has not been properly maintained and updated, reflecting changes in ship structure and equipment, taking into account the relevant IMO guidelines;

(b) where the renewal survey is not completed within the intervals specified in Article 8(5).

3. A ready for recycling certificate shall be issued by the administration or by a recognised organisation authorised by it for a period not exceeding three months.

4. A ready for recycling certificate issued under Article 9(9) shall cease to be valid where the condition of the ship does not correspond substantially with the particulars of the inventory certificate.

5. By way of derogation from paragraph 3, the ready for recycling certificate may be extended by the administration or by a recognised organisation authorised by it for a single point to point voyage to the ship recycling facility.

Article 11

Port State control

1. Member States shall apply control provisions for ships in accordance with their national law having regard to Directive 2009/16/EC. Subject to paragraph 2, any such inspection shall

be limited to checking that either an inventory certificate or a ready for recycling certificate is kept on board, which, if valid, shall be considered sufficient for the inspection to be approved.

2. A detailed inspection may be carried out by the relevant authority involved in port State control activities, taking into account the relevant IMO guidelines, where a ship does not carry a valid certificate or there are clear grounds for believing either that:

(a) the condition of the ship or its equipment does not correspond substantially with the particulars of that certificate, Part I of the inventory of hazardous materials, or both; or

(b) there is no procedure implemented on board the ship for the maintenance of Part I of the inventory of hazardous materials.

3. A ship may be warned, detained, dismissed or excluded from the ports or offshore terminals under the jurisdiction of a Member State in the event that it fails to submit to the relevant authorities of that Member State a copy of the inventory certificate or the ready for recycling certificate, as appropriate and on request of those authorities, without prejudice to Article 9. A Member State taking such action shall immediately inform the administration concerned. Failure to update the inventory of hazardous materials shall not constitute a detainable deficiency, but any inconsistencies in the inventory of hazardous materials shall be reported to the administration concerned and shall be rectified at the time of the next survey.

4. Access to a specific port or anchorage may be permitted by the relevant authority of a Member State in the event of force majeure or overriding safety considerations, or to reduce or minimise the risk of pollution or to have deficiencies rectified, provided that adequate measures to the satisfaction of the relevant authority of that Member State have been implemented by the owner, the operator or the master of the ship to ensure safe entry.

Article 12

Requirements for ships flying the flag of a third country

1. Subject to point (b) of Article 32(2), when calling at a port or anchorage of a Member State, a ship flying the flag of a third country shall have on board an inventory of hazardous materials that complies with Article 5(2).

Notwithstanding the first subparagraph, access to a specific port or anchorage may be permitted by the relevant authority of a Member State in the event of force majeure or overriding safety considerations, or to reduce or minimise the risk of pollution or to have deficiencies rectified, provided that adequate measures to the satisfaction of the relevant authority of that Member State have been implemented by the owner, the operator or the master of the ship to ensure safe entry.

2. The installation of hazardous materials referred to in Annex I on ships flying the flag of a third country, whilst in a port or anchorage of a Member State, shall be prohibited or restricted as specified in Annex I.

The use of hazardous materials referred to in Annex I on ships flying the flag of a third country, whilst in a port or anchorage of a Member State, shall be prohibited or restricted as specified in Annex I, without prejudice to the exemptions and transitional arrangements applicable to those materials under international law.

3. The inventory of hazardous materials shall be specific to each ship, be compiled taking into account the relevant IMO guidelines and serve to clarify that the ship complies with paragraph 2 of this Article. When the inventory of hazardous materials is developed it shall identify, at least, the hazardous materials listed in Annex I. A plan shall be established by the ship flying the flag of a third country describing the visual/sampling check by which the inventory of hazardous materials is developed taking into account the relevant IMO guidelines.

4. The inventory of hazardous materials shall be properly maintained and updated throughout the operational life of the ship, reflecting new installations containing any hazardous materials referred to in Annex II and relevant changes in the structure and equipment of the ship, taking into account the exemptions and transitional arrangements applicable to those materials under international law.

5. A ship flying the flag of a third country may be warned, detained, dismissed or excluded from the ports or offshore terminals under the jurisdiction of a Member State in the event that it fails to submit to the relevant authorities of that Member State a copy of the statement of compliance in accordance with paragraphs 6 and 7, together with the inventory of hazardous materials, as appropriate and on request from those authorities. A Member State taking such action shall immediately inform the relevant authorities of the third country whose flag the ship concerned is flying. Failure to update the inventory of hazardous materials shall not constitute a detainable deficiency, but any inconsistencies in the inventory of hazardous materials shall be reported to the relevant authorities of the third country whose flag that ship is flying.

6. The statement of compliance shall be issued after verification of the inventory of hazardous materials by the relevant authorities of the third country whose flag the ship is flying or an organisation authorised by them, in accordance with the national requirements. The statement of compliance may be modelled on the basis of Appendix 3 to the Hong Kong Convention.

7. The statement of compliance and the inventory of hazardous materials shall be drawn up in an official language of the issuing relevant authorities of the third country whose

flag the ship is flying and where the language used is not English, French or Spanish, the text shall include a translation into one of those languages.

8. Subject to point (b) of Article 32(2), ships flying the flag of a third country applying to be registered under the flag of a Member State shall ensure that an inventory of hazardous materials, as provided for in Article 5(2), is kept on board or is established within six months of the registration under the flag of that Member State or during any of the next surveys under Article 8(3), whichever comes first.

TITLE III

SHIP RECYCLING FACILITIES

Article 13

Requirements necessary for ship recycling facilities to be included in the European List

1. In order to be included in the European List, a ship recycling facility shall comply with the following requirements, in accordance with the relevant Hong Kong Convention provisions and taking into account the relevant guidelines of the IMO, the ILO, the Basel Convention and of the Stockholm Convention on Persistent Organic Pollutants and of other international guidelines:

- (a) it is authorised by its competent authorities to conduct ship recycling operations;
- (b) it is designed, constructed and operated in a safe and environmentally sound manner;
- (c) it operates from built structures;
- (d) it establishes management and monitoring systems, procedures and techniques which have the purpose of preventing, reducing, minimising and to the extent practicable eliminating:
 - (i) health risks to the workers concerned and to the population in the vicinity of the ship recycling facility, and
 - (ii) adverse effects on the environment caused by ship recycling;
- (e) it prepares a ship recycling facility plan;

- (f) it prevents adverse effects on human health and the environment, including the demonstration of the control of any leakage, in particular in intertidal zones;
- (g) it ensures safe and environmentally sound management and storage of hazardous materials and waste, including:
 - (i) the containment of all hazardous materials present on board during the entire ship recycling process so as to prevent any release of those materials into the environment; and in addition, the handling of hazardous materials, and of waste generated during the ship recycling process, only on impermeable floors with effective drainage systems;
 - (ii) that all waste generated from the ship recycling activity and their quantities are documented and are only transferred to waste management facilities, including waste recycling facilities, authorised to deal with their treatment without endangering human health and in an environmentally sound manner;
- (h) it establishes and maintain an emergency preparedness and response plan; ensures rapid access for emergency response equipment, such as fire-fighting equipment and vehicles, ambulances and cranes, to the ship and all areas of the ship recycling facility;
- (i) it provides for worker safety and training, including ensuring the use of personal protective equipment for operations requiring such use;
- (j) it establishes records on incidents, accidents, occupational diseases and chronic effects and, if requested by its competent authorities, reports any incidents, accidents, occupational diseases or chronic effects causing, or with the potential for causing, risks to workers' safety, human health and the environment;
- (k) it agrees to comply with the requirements of paragraph 2.

2. The operator of a ship recycling facility shall:

- (a) send the ship recycling plan, once approved in accordance with Article 7(3), to the ship owner and the administration or a recognised organisation authorised by it;
- (b) report to the administration that the ship recycling facility is ready in every respect to start the recycling of the ship;
- (c) when the total or partial recycling of a ship is completed in accordance with this Regulation, within 14 days of the date of the total or partial recycling in accordance with the ship recycling plan, send a statement of completion to the administration which issued the ready for recycling certificate for the ship. The statement of completion shall include a report on incidents and accidents damaging human health and/or the environment, if any.

3. The Commission shall adopt implementing acts to establish the format of:

- (a) the report required by point (b) of paragraph 2 of this Article to ensure it is consistent with Appendix 6 to the Hong Kong Convention; and
- (b) the statement required by point (c) of paragraph 2 of this Article to ensure it is consistent with Appendix 7 to the Hong Kong Convention.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25 of this Regulation.

Article 14

Authorisation of ship recycling facilities located in a Member State

1. Without prejudice to other relevant provisions of Union law, competent authorities shall authorise ship recycling facilities located on their territory that comply with the requirements set out in Article 13 to conduct ship recycling. That authorisation may be granted to the respective ship recycling facilities for a maximum period of five years and renewed accordingly.

Provided that the requirements of this Regulation are complied with, any permit produced pursuant to other relevant national or Union law provisions may be combined with the authorisation under this Article to form a single permit, where such a format obviates the unnecessary duplication of information and the duplication of work by the operator of the ship recycling facility or the ship recycling company or the competent authority. In those cases the authorisation may be extended in accordance with the permit regime referred to in the first subparagraph, but not exceeding a maximum period of five years.

2. Member States shall establish and update a list of the ship recycling facilities that they have authorised in accordance with paragraph 1.

3. The list referred to in paragraph 2 shall be communicated to the Commission without delay and not later than 31 March 2015.

4. Where a ship recycling facility ceases to comply with the requirements set out in Article 13, the Member State where that ship recycling facility is located shall suspend or withdraw the authorisation given to it or require corrective actions by the ship recycling company concerned and shall inform the Commission thereof without delay.

5. Where a ship recycling facility has been authorised in accordance with paragraph 1, the Member State concerned shall inform the Commission thereof without delay.

Article 15

Ship recycling facilities located in a third country

1. A ship recycling company owning a ship recycling facility located in a third country and intending to recycle ships flying the flag of a Member State shall submit an application to the Commission for inclusion of that ship recycling facility in the European List.

2. The application referred to in paragraph 1 shall be accompanied by evidence that the ship recycling facility concerned complies with the requirements set out in Article 13 in order to conduct ship recycling and to be included in the European List in accordance with Article 16.

In particular, the ship recycling company shall:

- (a) identify the permit, license or authorisation granted by its competent authorities to conduct the ship recycling and, where relevant, the permit, license or authorisation granted by the competent authorities to all its contractors and sub-contractors directly involved in the process of ship recycling and specify all information referred to in Article 16(2);
- (b) indicate whether the ship recycling plan will be approved by the competent authority through a tacit or explicit procedure, specifying the review period relating to tacit approval, in accordance with national requirements, where applicable;
- (c) confirm that it will only accept a ship flying the flag of a Member State for recycling in accordance with this Regulation;
- (d) provide evidence that the ship recycling facility is capable of establishing, maintaining and monitoring of the safe-for-hot work and safe-for-entry criteria throughout the ship recycling process;
- (e) attach a map of the boundary of the ship recycling facility and the location of ship recycling operations within it;
- (f) for each hazardous material referred to in Annex I and additional hazardous material which might be part of the structure of a ship, specify:
 - (i) whether the ship recycling facility is authorised to carry out the removal of the hazardous material. Where it is so authorised, the relevant personnel authorised to carry out the removal shall be identified and evidence of their competence shall be provided;
 - (ii) which waste management process will be applied within or outside the ship recycling facility such as incineration, landfilling or another waste treatment method, the name and address of the waste treatment facility if different from that of the ship recycling facility, and provide

evidence that the applied process will be carried out without endangering human health and in an environmentally sound manner;

- (g) confirm that the company adopted a ship recycling facility plan, taking into account the relevant IMO guidelines;
- (h) provide the information necessary to identify the ship recycling facility.

3. The Commission shall be empowered to adopt implementing acts to specify the format of the information required to identify the ship recycling facility. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25.

4. In order to be included in the European List, compliance by ship recycling facilities located in third countries with the requirements set out in Article 13 shall be certified following a site inspection by an independent verifier with appropriate qualifications. The certification shall be submitted to the Commission by the ship recycling company when applying for inclusion in the European List and, every five years thereafter, upon renewal of the inclusion in the European List. The initial inclusion on the list and the renewal thereof shall be supplemented by a mid-term review to confirm compliance with the requirements set out in Article 13.

By applying for inclusion in the European List, ship recycling companies accept the possibility of the ship recycling facility concerned being subject to site inspections by the Commission or agents acting on its behalf prior to or after their inclusion in the European List in order to verify compliance with the requirements set out in Article 13. The independent verifier, the Commission or agents acting on its behalf shall cooperate with the competent authorities of the third country where the ship recycling facility is located in order to carry out those site inspections.

The Commission may issue technical guidance notes in order to facilitate such certification.

5. For the purposes of Article 13, with regard to the waste recovery or disposal operation concerned, environmentally sound management may only be assumed to be in place provided the ship recycling company can demonstrate that the waste management facility which receives the waste will be operated in accordance with human health and environmental protection standards that are broadly equivalent to relevant international and Union standards.

6. The ship recycling company shall provide updated evidence without delay in the event of any changes to the information provided to the Commission and shall, in any event, three months prior to expiry of each five year period of inclusion on the European List, declare that:

- (a) the evidence that it has provided is complete and up-to-date;
- (b) the ship recycling facility continues and will continue to comply with the requirements of Article 13.

Article 16

Establishment and updating of the European List

1. The Commission shall adopt implementing acts to establish a European List of ship recycling facilities which:

- (a) are located in the Union and have been notified by the Member States in accordance with Article 14(3);
- (b) are located in a third country and whose inclusion is based on an assessment of the information and supporting evidence provided or gathered in accordance with Article 15.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25.

2. The European List shall be published in the *Official Journal of the European Union* and on the website of the Commission not later than 31 December 2016. It shall be divided into two sub-lists indicating the ship recycling facilities located in a Member State and the ship recycling facilities located in a third country.

The European List shall include all of the following information about the ship recycling facility:

- (a) the method of recycling;
- (b) the type and size of ships that can be recycled;
- (c) any limitation and conditions under which the ship recycling facility operates, including as regards hazardous waste management;
- (d) details on the explicit or tacit procedure, as referred to in Article 7(3), for the approval of the ship recycling plan by the competent authority;
- (e) the maximum annual ship recycling output.

3. The European List shall indicate the date of expiry of the inclusion of the ship recycling facility. An inclusion shall be valid for a maximum period of five years and shall be renewable.

4. The Commission shall adopt implementing acts to regularly update the European List, in order to:

- (a) include a ship recycling facility in the European List where:
 - (i) it has been authorised in accordance with Article 14; or
 - (ii) its inclusion in the European List is decided in accordance with paragraph 1(b) of this Article;

- (b) remove a ship recycling facility from the European List where:

- (i) the ship recycling facility ceases to comply with the requirements set out in Article 13; or
- (ii) the updated evidence is not provided at least three months prior to expiry of the five-year period as set out in paragraph 3 of this Article.

Those implementing acts shall be adopted, in accordance with the examination procedure referred to in Article 25.

5. In establishing and updating the European List, the Commission shall act in accordance with the principles enshrined in the Treaties and with the international obligations of the Union.

6. Member States shall communicate to the Commission all information that may be relevant in the context of updating the European List. The Commission shall forward all relevant information to the other Member States.

TITLE IV

GENERAL ADMINISTRATIVE PROVISIONS

Article 17

Language

1. The ship recycling plan referred to in Article 7 shall be developed in a language accepted by the state authorising the ship recycling facility. Where the language used is not English, French or Spanish, the ship recycling plan shall be translated into one of those languages, except where the administration is satisfied that that is unnecessary.

2. The inventory certificate and the ready for recycling certificate issued pursuant to Article 9 shall be drawn up in an official language of the issuing administration. Where the language used is not English, French or Spanish, the text shall include a translation into one of those languages.

Article 18

Designation of competent authorities and administrations

1. Member States shall designate the competent authorities and administrations responsible for the application of this Regulation and shall notify the Commission of those designations. Member States shall immediately notify the Commission of any changes in such information.

2. The Commission shall publish on its website lists of the designated competent authorities and administrations and shall update those lists as appropriate.

*Article 19***Designation of contact persons**

1. Member States and the Commission shall each designate one or more contact persons responsible for informing or advising natural or legal persons making enquiries. The contact person of the Commission shall forward to the contact persons of the Member States any questions received which concern the latter, and vice versa.

2. Member States shall notify the Commission of the designation of contact persons. Member States shall immediately notify the Commission of any changes to that information.

3. The Commission shall publish on its website lists of the designated contact persons and shall update those lists as appropriate.

*Article 20***Meeting of contact persons**

The Commission shall, if requested by Member States or where it considers it appropriate, periodically organise a meeting of the contact persons to discuss the questions raised by the implementation of this Regulation. Relevant stakeholders shall be invited to such meetings, or parts of meetings, where all Member States and the Commission are in agreement that it is appropriate to do so.

TITLE V

REPORTING AND ENFORCEMENT*Article 21***Reports by the Member States**

1. Each Member State shall send to the Commission a report containing the following:

- (a) a list of the ships flying its flag to which a ready for recycling certificate has been issued, and the name of the ship recycling company and the location of the ship recycling facility as shown in the ready for recycling certificate;
- (b) a list of the ships flying its flag for which a statement of completion has been received;
- (c) information regarding illegal ship recycling, penalties and follow-up actions undertaken by the Member State.

2. Every three years, Member States shall electronically transmit the report to the Commission no later than nine months after the end of the three-year period covered by it.

The first electronic report shall cover the period from the date of application of this Regulation to the end of the first regular three-year reporting period, specified in Article 5 of Council Directive 91/692/EEC ⁽¹⁾, falling after the starting date of the first reporting period.

⁽¹⁾ Council Directive 91/692/EEC of 23 December 1991 standardizing and rationalizing reports on the implementation of certain Directives relating to the environment (OJ L 377, 31.12.1991, p. 48).

The Commission shall publish a report on the application of this Regulation no later than nine months after receiving the reports from the Member States.

3. The Commission shall enter this information in an electronic database that is permanently accessible to the public.

*Article 22***Enforcement in Member States**

1. Member States shall lay down provisions on penalties applicable to infringements of this Regulation and shall take all the measures necessary to ensure that they are applied. The penalties provided for shall be effective, proportionate and dissuasive.

2. Member States shall cooperate, bilaterally or multilaterally, with one another in order to facilitate the prevention and detection of potential circumvention and breach of this Regulation.

3. Member States shall designate those members of their permanent staff responsible for the cooperation referred to in paragraph 2. That information shall be sent to the Commission, which shall distribute to those members a compiled list.

4. Member States shall communicate to the Commission the provisions of their national law relating to the enforcement of this Regulation and the applicable penalties.

*Article 23***Request for action**

1. Natural or legal persons affected or likely to be affected by a breach of Article 13 in conjunction with Article 15 and Article 16(1)(b) of this Regulation, or having a sufficient interest in environmental decision-making relating to the breach of Article 13 in conjunction with Article 15 and Article 16(1)(b) of this Regulation shall be entitled to request the Commission to take action under this Regulation with respect to such a breach or an imminent threat of such a breach.

The interest of any non-governmental organisation promoting environmental protection and meeting the requirements laid down in Article 11 of Regulation (EC) No 1367/2006 of the European Parliament and of the Council ⁽²⁾ shall be deemed sufficient for the purposes of the first subparagraph.

⁽²⁾ Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13).

2. The request for action shall be accompanied by the relevant information and data supporting that request.

3. Where the request for action and the accompanying information and data show in a plausible manner that a breach of Article 13 in conjunction with Article 15 and Article 16(1)(b) has occurred, or that there is an imminent threat of such a breach, the Commission shall consider any such requests for action and information and data. In such circumstances, the Commission shall give the ship recycling company concerned an opportunity to make its views known with respect to the request for action and the accompanying information and data.

4. The Commission shall, without delay and in accordance with the relevant provisions of Union law, inform the persons who submitted a request pursuant to paragraph 1, of its decision to accede to or refuse the request for action and shall provide the reasons for it.

TITLE VI

FINAL PROVISIONS

Article 24

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 5(8) shall be conferred on the Commission for a period of five years from 30 December 2013. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension no later than three months before the end of each period.

3. The delegation of power referred to in Article 5(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 5(8) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have

both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 25

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. When reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 26

Transitional provision

As of the date of publication of the European List, Member States may, prior to the date of application of this Regulation, authorise the recycling of ships in ship recycling facilities included in the European List. In such circumstances, Regulation (EC) No 1013/2006 shall not apply.

Article 27

Amendment to Regulation (EC) No 1013/2006

In Article 1(3) of Regulation (EC) No 1013/2006, the following point is added:

- '(i) ships flying the flag of a Member State falling under the scope of Regulation (EU) No 1257/2013 of the European Parliament and of the Council (*).

(*) Regulation (EU) No 1257/2013 of the European Parliament and of the Council of 20 November 2013 on ship recycling and amending Regulation (EC) No 1013/2006 and Directive 2009/16/EC (OJ L 330, 10.12.2013, p. 1).'

Article 28

Amendment to Directive 2009/16/EC

In Annex IV, the following point is added:

- '49. A certificate on the inventory of hazardous materials or a statement of compliance as applicable pursuant to Regulation (EU) No 1257/2013 of the European Parliament and of the Council (*).

(*) Regulation (EU) No 1257/2013 of the European Parliament and of the Council of 20 November 2013 on ship recycling and amending Regulation (EC) No 1013/2006 and Directive 2009/16/EC (OJ L 330, 10.12.2013, p. 1).'

Article 29

Financial incentive

The Commission shall, by 31 December 2016, submit to the European Parliament and to the Council a report on the feasibility of a financial instrument that would facilitate safe and sound ship recycling and shall, if appropriate, accompany it by a legislative proposal.

Article 30

Review

1. The Commission shall assess which infringements of this Regulation should be brought under the scope of Directive 2008/99/EC to achieve equivalence of the provisions related to infringements between this Regulation and Regulation (EC) No 1013/2006. The Commission shall report on its findings by 31 December 2014 to the European Parliament and to the Council and, if appropriate, accompany it by a legislative proposal.

2. The Commission shall review this Regulation not later than 18 months prior to the date of entry into force of the Hong Kong Convention and at the same time, submit, if appropriate, any appropriate legislative proposals to that effect. This review shall consider the inclusion of ship recycling facilities authorised under the Hong Kong Convention in the European List in order to avoid duplication of work and administrative burden.

3. The Commission shall keep this Regulation under review and, if appropriate, make timely proposals to address developments relating to international Conventions, including the Basel Convention, should it prove necessary.

4. Notwithstanding paragraph 2, the Commission shall, by five years after the date of application of this Regulation, submit a report to the European Parliament and to the Council on the application of this Regulation, accompanied, if appropriate, by legislative proposals to ensure that its objectives are being met and its impact is ensured and justified.

Article 31

Entry into force

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

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

Done at Strasbourg, 20 November 2013.

For the European Parliament
The President
M. SCHULZ

Article 32

Application

1. This Regulation shall apply from the earlier of the following two dates, but not earlier than 31 December 2015:

(a) 6 months after the date that the combined maximum annual ship recycling output of the ship recycling facilities included in the European List constitutes not less than 2,5 million light displacement tonnes (LDT). The annual ship recycling output of a ship recycling facility is calculated as the sum of the weight of ships expressed in LDT that have been recycled in a given year in that facility. The maximum annual ship recycling output is determined by selecting the highest value occurring in the preceding 10-year period for each ship recycling facility, or, in the case of a newly authorised ship recycling facility, the highest annual value achieved at that facility; or

(b) on 31 December 2018.

2. However in relation to the following provisions the following dates of application shall apply:

(a) Article 2, the second subparagraph of Article 5(2), Articles 13, 14, 15, 16, 25 and 26 from 31 December 2014;

(b) the first and third subparagraphs of Article 5(2) and Article 12(1) and (8) from 31 December 2020.

3. The Commission shall publish in the *Official Journal of the European Union* a notice concerning the date of application of this Regulation when the conditions referred to in point (a) of paragraph 1 have been fulfilled.

4. If a Member State has closed its national ship register or, during a three year period, has had no ships registered under its flag, and as long as no ship is registered under its flag, that Member State may derogate from the provisions of this Regulation, except for Articles 4, 5, 11, 12, 13, 14, 16(6), 18, 19, 20, 21 and 22. Where a Member State intends to avail itself of this derogation, it shall notify the Commission at the latest on the date of application of this Regulation. Any subsequent change shall also be communicated to the Commission.

For the Council
The President
V. LEŠKEVIČIUS

ANNEX I

CONTROL OF HAZARDOUS MATERIALS

Hazardous Material	Definitions	Control measures
Asbestos	Materials containing asbestos	For all ships, new installation of materials which contain asbestos shall be prohibited.
Ozone-depleting substances	Controlled substances defined in Article 1(4) of the Montreal Protocol on Substances that Deplete the Ozone Layer, 1987, listed in Annexes A,B,C or E to that Protocol in force at the time of application or interpretation of this Annex. Ozone-depleting substances that may be found on board ships include, but are not limited to: Halon 1211 Bromochlorodifluoromethane Halon 1301 Bromotrifluoromethane Halon 2402 1,2-Dibromo-1,1,2,2-tetrafluoroethane (also known as Halon 114B2) CFC-11 Trichlorofluoromethane CFC-12 Dichlorodifluoromethane CFC-113 1,1,2-Trichloro-1,2,2-trifluoroethane CFC-114 1,2-Dichloro-1,1,2,2-tetrafluoroethane CFC-115 Chloropentafluoroethane HCFC-22 Chlorodifluoromethane	New installations which contain ozone-depleting substances shall be prohibited on all ships.
Polychlorinated biphenyls (PCB)	'Polychlorinated biphenyls' means aromatic compounds formed in such a manner that the hydrogen atoms on the biphenyl molecule (two benzene rings bonded together by a single carbon-carbon bond) may be replaced by up to ten chlorine atoms	For all ships, new installation of materials which contain Polychlorinated biphenyls shall be prohibited.
Perfluorooctane sulfonic acid (PFOS) ⁽¹⁾	'perfluorooctane sulfonic acid' (PFOS) means perfluorooctane sulfonic acid and its derivatives	New installations which contain perfluorooctane sulfonic acid (PFOS) and its derivatives shall be prohibited in accordance with Regulation (EC) No 850/2004 of the European Parliament and of the Council ⁽²⁾ .
Anti-fouling compounds and systems	Anti-fouling compounds and systems regulated under Annex I to the International Convention on the Control of Harmful Anti-fouling Systems on Ships, 2001 (AFS Convention) in force at the time of application or interpretation of this Annex.	1. No ship may apply anti-fouling systems containing organotin compounds as a biocide or any other anti-fouling system whose application or use is prohibited by the AFS Convention.

Hazardous Material	Definitions	Control measures
		2. No new ship or new installations on ships shall apply or employ anti-fouling compounds or systems in a manner inconsistent with the AFS Convention.

⁽¹⁾ Not applicable for ships flying the flag of a third country.

⁽²⁾ Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7).

*ANNEX II***LIST OF ITEMS FOR THE INVENTORY OF HAZARDOUS MATERIALS**

1. Any hazardous materials listed in Annex I
 2. Cadmium and Cadmium Compounds
 3. Hexavalent Chromium and Hexavalent Chromium Compounds
 4. Lead and Lead Compounds
 5. Mercury and Mercury Compounds
 6. Polybrominated Biphenyl (PBBs)
 7. Polybrominated Diphenyl Ethers (PBDEs)
 8. Polychlorinated Naphthalenes (more than 3 chlorine atoms)
 9. Radioactive Substances
 10. Certain Shortchain Chlorinated Paraffins (Alkanes, C10-C13, chloro)
 11. Brominated Flame Retardant (HBCDD)
-

REGULATION (EU) No 1258/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 November 2013
amending Regulation (EC) No 273/2004 on drug precursors
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) On 7 January 2010, the Commission adopted a report pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council ⁽³⁾ on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors.
- (2) In that report, the Commission recommended further analysing ways to strengthen the control of the trade of acetic anhydride, a scheduled substance in category 2 of Annex I to Regulation (EC) No 273/2004, pursuant to Article 2(a) of that Regulation, in order to better prevent the diversion of acetic anhydride for the illicit production of heroin.
- (3) In its Conclusions of 25 May 2010 on the functioning and implementation of the EU drug precursors legislation, the Council invited the Commission to propose legislative amendments after carefully assessing their potential impact on Member States' authorities and economic operators.
- (4) This Regulation clarifies the definition of a scheduled substance: in this regard, the term 'pharmaceutical preparation', which stems from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on

19 December 1988, is deleted as it is already covered by the relevant terminology of Union legal acts, namely 'medicinal products'. Moreover, the term 'other preparations' is deleted as it duplicates the term 'mixtures' already used in that definition.

- (5) A definition of the term 'user' should be introduced for persons possessing substances for purposes other than placing them on the market and it should be clarified that persons using scheduled substances in category 1 of Annex I to Regulation (EC) No 273/2004 for other purposes than placing them on the market are obliged to obtain a licence.
- (6) More detailed rules on registration should be introduced to ensure uniform conditions of registration in all Member States for scheduled substances in category 2 of Annex I to Regulation (EC) No 273/2004. For substances scheduled in a new subcategory 2A of Annex I to that Regulation, in addition to operators users should also be subject to a registration requirement.
- (7) Where fees are levied for obtaining a licence or registration, Member States should consider adjusting such fees in order to safeguard the competitiveness of micro-enterprises.
- (8) It should be made clear that Member States have the possibility to act with regard to suspicious transactions involving non-scheduled substances in order to enable them to react more quickly with regard to new trends in the illicit production of drugs.
- (9) A European database on drug precursors ('the European database') should be created to simplify the reporting by Member States with regard to seizures and stopped shipments, where possible in an aggregated and anonymised manner and in the least intrusive manner as regards the processing of personal data, taking into account the state of the art of privacy-enhancing technologies and the principle of data limitation. The European database should also serve as a European register of operators and users holding a licence or registration which will facilitate verification of the legitimacy of commercial transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their transactions involving scheduled substances.

⁽¹⁾ OJ C 76, 14.3.2013, p. 54.

⁽²⁾ Position of the European Parliament of 23 October 2013 (not yet published in the Official Journal) and decision of the Council of 15 November 2013.

⁽³⁾ Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).

(10) Regulation (EC) No 273/2004, as amended by this Regulation, envisages the processing of information, including the processing of personal data, for the purposes of enabling the competent authorities to monitor the placing on the market of drug precursors and to

prevent the diversion of scheduled substances. The processing of personal data should be carried out in a manner compatible with the purpose of that Regulation and in accordance with Directive 95/46/EC of the European Parliament and of the Council⁽¹⁾ and Regulation (EC) No 45/2001 of the European Parliament and of the Council⁽²⁾ and, in particular, with Union requirements relating to data quality, proportionality, purpose limitation, and rights to information, access, rectification of data, erasure and blocking, organisational and technical measures and international transfers of personal data.

- (11) The processing of personal data for the purposes of Regulation (EC) No 273/2004, as amended by this Regulation, and any delegated and implementing acts adopted pursuant thereto should respect the fundamental right to respect for private and family life recognised by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms as well as the rights to respect for private and family life, and the right to the protection of personal data recognised, respectively, by Articles 7 and 8 of the Charter of Fundamental Rights of the European Union. The delegated and implementing acts should also ensure that any processing of personal data takes place in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001.
- (12) Acetic anhydride, currently scheduled in category 2 of Annex I to Regulation (EC) No 273/2004, should be included in a new subcategory 2A of Annex I thereto to allow increased control of its trade. The remaining substances of category 2 of Annex I to Regulation (EC) No 273/2004 should be listed as subcategory 2B of Annex I thereto.
- (13) Regulation (EC) No 273/2004 confers powers on the Commission in order to implement some of its provisions, to be exercised in accordance with the procedures laid down in Council Decision 1999/468/EC⁽³⁾.
- (14) As a consequence of the entry into force of the Treaty of Lisbon, those powers should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).
- (15) In order to achieve the objectives of Regulation (EC) No 273/2004, as amended by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should

be delegated to the Commission to specify the requirements and conditions for the granting of the licence and registration, for listing operators and users having obtained a licence or registration in the European database, for obtaining and using customer declarations, for the documentation and labelling of mixtures containing scheduled substances, for the provision of information by the operators on transactions involving scheduled substances, and for information to be provided by Member States on the implementation of the monitoring measures laid down in Regulation (EC) No 273/2004, and in order to amend the Annexes thereto. Such delegated acts should also determine the categories of personal data which can be processed by Member States and operators pursuant to Regulation (EC) No 273/2004, the categories of personal data which can be stored in the European database and the safeguards for the processing of personal data. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure the simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

- (16) It is also important that the Commission seek the opinion of the European Data Protection Supervisor when preparing delegated acts relating to the processing of personal data.
- (17) In order to ensure uniform conditions for the implementation of Regulation (EC) No 273/2004, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽⁴⁾. The examination procedure should be used for the adoption of the implementing acts in order to set up details on how customer declarations should be provided in electronic form and on how to provide the information about transactions of operators with scheduled substances to a European database.
- (18) Since the objective of this Regulation, namely to strengthen the rules for registration of operators placing on the market or possessing scheduled substances of category 2 of Annex I to Regulation (EC) No 273/2004, in particular acetic anhydride, in order to prevent its diversion towards the illicit production of drugs, cannot be sufficiently achieved by the Member States because traffickers gain from national differences in registration and move their illicit business where drug precursors are easiest to divert, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In

⁽¹⁾ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

⁽²⁾ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

⁽³⁾ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

⁽⁴⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

- (19) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 18 January 2013 ⁽¹⁾.
- (20) Regulation (EC) No 273/2004 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 273/2004 is amended as follows:

- (1) Article 1 is replaced by the following:

‘Article 1

Scope and objectives

This Regulation establishes harmonised measures for the intra-Union control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances with a view to preventing the diversion of such substances.’;

- (2) in Article 2:

- (a) point (a) is replaced by the following:

‘(a) “scheduled substance” means any substance listed in Annex I that can be used for the illicit manufacture of narcotic drugs or psychotropic substances, including mixtures and natural products containing such substances but excluding mixtures and natural products which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council (*) and veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council (**);

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

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

- (b) point (c) is replaced by the following:

‘(c) “placing on the market” means any supply, whether in return for payment or free of charge, of scheduled substances in the Union; or the storage, manufacture, production, processing, trade, distribution or brokering of these substances for the purpose of supply in the Union;’;

- (c) the following points are added:

‘(h) “user” means a natural or legal person other than an operator who possesses a scheduled substance and is engaged in the processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances;

(i) “natural product” means an organism or a part thereof, in any form, or any substances which occur in nature as defined in point 39 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (*).

(*) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).’;

- (3) in Article 3:

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

‘2. Operators and users shall obtain a licence from the competent authorities of the Member State in which they are established before they may possess or place on the market scheduled substances of category 1 of Annex I. The competent authorities may grant special licences to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or armed forces. Such special licences shall be valid only for the use of scheduled substances of category 1 of Annex I within the scope of the official duties of the operators concerned.

3. Any operator holding a licence shall supply scheduled substances of category 1 of Annex I only to operators or users who also hold a licence and have signed a customer declaration as provided for in Article 4(1).’;

- (b) paragraphs 5, 6 and 7 are replaced by the following:

‘5. Without prejudice to paragraph 8, the competent authorities may either limit the validity of the licence to a period not exceeding three years or

⁽¹⁾ Not yet published in the Official Journal.

may oblige the operators and users to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled. The licence shall mention the operation or operations for which it is valid, as well as the scheduled substances concerned. The competent authorities shall, in principle, grant special licences for an unlimited duration but may suspend or revoke them where there are reasonable grounds for believing that the holder is no longer a fit and proper person to hold a licence, or that the conditions under which the licence was granted are no longer fulfilled.

6. Operators shall obtain registration from the competent authorities of the Member State in which they are established before placing on the market scheduled substances of category 2 of Annex I. From 1 July 2015 users shall obtain a registration from the competent authorities of the Member State in which they are established before possessing scheduled substances of subcategory 2A of Annex I. The competent authorities may grant special registrations to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces. Such special registrations shall be considered valid only for the use of scheduled substances of category 2 of Annex I within the scope of the official duties of the operators or users concerned.

6a. Any operator holding a registration shall supply scheduled substances of subcategory 2A of Annex I only to other operators or users who also hold a registration and have signed a customer declaration as provided for in Article 4(1).

6b. When considering whether to grant registration, the competent authorities shall take into account, in particular, the competence and integrity of the applicant. They shall refuse registration if there are reasonable grounds for doubting the suitability and reliability of the applicant or of the officer responsible for the trade in scheduled substances. They may suspend or revoke registration where there are reasonable grounds for believing that the holder is no longer a fit and proper person to hold a registration, or that the conditions under which registration was granted are no longer fulfilled.

6c. The competent authorities may require operators and users to pay a fee for the application for a licence or for registration.

Where a fee is levied, competent authorities shall consider adjusting the level of the fee depending on the size of the enterprise. Such a fee shall be levied in a non-discriminatory manner and shall not exceed the cost of processing the application.

7. The competent authorities shall list the operators and users that have obtained a licence or a registration in the European database referred to in Article 13a.

8. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for:

- (a) granting the licence, including, where relevant, the categories of personal data to be provided;
- (b) granting registration, including where relevant the categories of personal data to be provided;
- (c) listing operators and users in the European database referred to in Article 13a, in accordance with paragraph 7 of this Article.

The categories of personal data referred to in points (a) and (b) of the first subparagraph of this paragraph shall not include special categories of data as referred to in Article 8(1) of Directive 95/46/EC of the European Parliament and of the Council (*).

(*) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).;

(4) in Article 4:

- (a) paragraph 1 is replaced by the following:

‘1. Without prejudice to paragraph 4 of this Article, and to Articles 6 and 14, any operator established within the Union who supplies a customer with a scheduled substance of category 1 or 2 of Annex I shall obtain a declaration from the customer which shows the specific use or uses of the scheduled substances. The operator shall obtain a separate declaration for each scheduled substance. That declaration shall conform to the model set out in point 1 of Annex III. In the case of legal persons, the declaration shall be made on headed notepaper.’;

- (b) paragraph 3 is replaced by the following:

‘3. An operator supplying scheduled substances of category 1 of Annex I shall stamp and date a copy of the declaration, certifying it to be a true copy of the original. Such copy shall always accompany those substances being moved within the Union and shall be presented on request to the authorities responsible for checking vehicle contents during transport operations.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for obtaining and using customer declarations.;

(5) in Article 5, the following paragraph is added:

‘7. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for the documentation of mixtures containing scheduled substances.;

(6) in Article 7, the following paragraph is added:

‘The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for the labelling of mixtures containing scheduled substances.;

(7) Article 8 is replaced by the following:

‘Article 8

Notification of the competent authorities

1. Operators shall notify the competent authorities immediately of any circumstances, such as unusual orders or transactions involving scheduled substances to be placed on the market, which suggest that such substances might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances. To that end, operators shall provide any available information allowing the competent authorities to verify the legitimacy of the relevant order or transaction.

2. Operators shall provide the competent authorities with relevant information in summary form about their transactions involving scheduled substances.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for operators to provide information as referred to in paragraph 2 of this Article including, where relevant, the categories of personal data to be processed for that purpose and the safeguards for processing such personal data.

4. Operators shall not disclose any personal data collected pursuant to this Regulation other than to the competent authorities.;

(8) in Article 9, paragraph 1 is replaced by the following:

‘1. The Commission shall draw up, and keep up to date, guidelines to facilitate cooperation between the competent authorities, the operators, and the chemical industry, in particular as regards non-scheduled substances.;

(9) in Article 10:

(a) points (b) and (c) of paragraph 1 are replaced by the following:

‘(b) to enter operators’ and users’ business premises in order to obtain evidence of irregularities;

(c) where necessary, to detain and seize consignments that fail to comply with this Regulation.;

(b) paragraph 2 is replaced by the following:

‘2. Each Member State may adopt the measures necessary to enable its competent authorities to control and monitor suspicious transactions involving non-scheduled substances, and in particular:

(a) to obtain information on any orders for non-scheduled substances or operations involving non-scheduled substances;

(b) to enter business premises in order to obtain evidence of suspicious transactions involving non-scheduled substances;

(c) where necessary, to detain and seize consignments to prevent the use of specific non-scheduled substances for the illicit manufacture of narcotic drugs or psychotropic substances.

3. The competent authorities shall respect confidential business information.;

(10) Articles 13 to 16 are replaced by the following:

‘Article 13

Communications from Member States

1. To permit any necessary adjustments to the arrangements for monitoring trade in scheduled substances and non-scheduled substances, the competent authorities in each Member State shall communicate to the Commission in electronic form via the European database referred to in Article 13a in a timely manner all relevant information on the implementation of the monitoring measures laid down in this Regulation, in particular as regards substances used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture, and their licit trade.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a specifying the conditions and requirements concerning the information to be provided under paragraph 1 of this Article.

3. A summary of the communications made pursuant to paragraph 1 of this Article shall be submitted by the Commission to the International Narcotics Control Board in accordance with Article 12(12) of the United Nations Convention and in consultation with the Member States.

Article 13a

European database on drug precursors

1. The Commission shall establish a European database on drug precursors with the following functions:

- (a) to facilitate the communication of information, where possible in an aggregated and anonymised manner, pursuant to Article 13(1), the synthesis and analysis of that information at the Union level, and the reporting to the International Narcotics Control Board pursuant to Article 13(3);
- (b) to create a European register of operators and users, which have been granted a licence or registration;
- (c) to enable operators to provide the competent authorities with information about their transactions in accordance with Article 8(2) in electronic form, as specified in implementing measures adopted pursuant to Article 14.

Personal data shall be included in the European database only after the adoption of the delegated acts referred to in Articles 3(8) and 8(3).

2. The Commission and the competent authorities shall take all necessary measures to ensure the security, confidentiality and accuracy of personal data contained in the European database and to ensure that the rights of data subjects are protected in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001 of the European Parliament and of the Council (*).

3. Information obtained pursuant to this Regulation, including personal data, shall be used in accordance with the applicable law on personal data protection and shall not be retained for longer than necessary for the purposes of this Regulation. The processing of special categories of data as referred to in Article 8(1) of Directive 95/46/EC and in Article 10(1) of Regulation (EC) No 45/2001 shall be prohibited.

4. The Commission shall make publicly available, in a clear, comprehensive and understandable manner, information concerning the European database in accordance with Articles 10 and 11 of Regulation (EC) No 45/2001.

Article 13b

Data protection

1. The processing of personal data by the competent authorities in the Member States shall be carried out in accordance with national laws, regulations and administrative provisions transposing Directive 95/46/EC and under the supervision of the supervisory authority of the Member State referred to in Article 28 of that Directive.

2. Without prejudice to Article 13 of Directive 95/46/EC, personal data obtained or processed pursuant to this Regulation shall be used solely for the purpose of preventing the diversion of scheduled substances.

3. The processing of personal data by the Commission, including for the purpose of the European database, shall be carried out in accordance with Regulation (EC) No 45/2001 and under the supervision of the European Data Protection Supervisor.

4. Member States and the Commission shall not process personal data in a manner incompatible with the purposes set out in Article 13a.

Article 14

Implementing acts

1. The Commission may adopt the following implementing acts:

- (a) rules on how to provide customer declarations referred to in Article 4 in electronic form, where appropriate;
- (b) rules on how to provide the information referred to in Article 8(2), including, where appropriate, in electronic form to a European database;
- (c) procedural rules for granting licences and registrations and for listing operators and users in the European database, as referred to in Article 3(2), (6) and (7).

2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14a(2).

Article 14a

Committee procedure

1. The Commission shall be assisted by the Drug Precursors Committee established by Article 30 of Council Regulation (EC) No 111/2005 (**). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (***).

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 15

Adaptation of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 15a in order to adapt Annexes I, II and III to new trends in diversion of drug precursors and to follow any amendment to the tables in the Annex to the United Nations Convention.

Article 15a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 3(8), 4(4) and 5(7), the second paragraph of Article 7, Articles 8(3) and 13(2) and Article 15 shall be conferred on the Commission for a period of five years from 30 December 2013. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 3(8), 4(4) and 5(7), the second paragraph of Article 7, Articles 8(3) and 13(2) and Article 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 3(8), 4(4) and 5(7), the second paragraph of Article 7, Articles 8(3) and 13(2) and Article 15 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 16

Information about measures adopted by Member States

1. Member States shall inform the Commission of the measures they adopt pursuant to this Regulation, and in particular of the measures adopted pursuant to Articles 10 and 12. They shall also notify any subsequent amendments thereof.

2. The Commission shall communicate that information to the other Member States.

3. The Commission shall, by 31 December 2019, submit a report to the European Parliament and to the Council on the implementation and functioning of this Regulation, and in particular on the possible need for additional action to monitor and control suspicious transactions with non-scheduled substances.

(*) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(**) Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).

(***) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).;

(11) in Annex I:

(a) the title is replaced by the following:

'List of scheduled substances';

(b) in category 1, the CN code for Norephedrine is replaced by the following:

'2939 44 00';

(c) in category 1, the following substance is added to the list of substances:

'Alpha-phenylacetoacetonitrile, CN code 2926 90 95, CAS No 4468-48-8';

(d) the text of category 2 is replaced by the text of the Annex to this Regulation;

(12) in Annex III, the text 'authorisation/' is deleted.

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 Strasbourg, 20 November 2013.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

V. LEŠKEVIČIUS

ANNEX

CATEGORY 2

SUBCATEGORY 2A

Substance	CN designation (if different)	CN code ⁽¹⁾	CAS No ⁽²⁾
Acetic anhydride		2915 24 00	108-24-7

The salts of the substances listed in this category, whenever the existence of such salts is possible.

SUBCATEGORY 2B

Substance	CN designation (if different)	CN code ⁽¹⁾	CAS No ⁽²⁾
Phenylacetic acid		2916 34 00	103-82-2
Anthranilic acid		2922 43 00	118-92-3
Piperidine		2933 32 00	110-89-4
Potassium permanganate		2841 61 00	7722-64-7

The salts of the substances listed in this category, whenever the existence of such salts is possible.

⁽¹⁾ OJ L 290, 28.10.2002, p. 1.

⁽²⁾ The CAS No is the 'chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different to those given.

**REGULATION (EU) No 1259/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 November 2013**

**amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade
between the Community and third countries in drug precursors**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

(1) On 7 January 2010, the Commission adopted a report, pursuant to Article 32 of Council Regulation (EC) No 111/2005 ⁽²⁾, on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors.

(2) Trade in medicinal products is not controlled in the existing Union control system for drug precursors, since they are currently excluded from the definition of scheduled substances.

(3) The Commission report pointed out that medicinal products containing ephedrine and pseudoephedrine were diverted into the illicit drug manufacture outside the Union, as a substitute for internationally controlled ephedrine and pseudoephedrine. The Commission therefore recommended strengthening the control of international trade in medicinal products containing ephedrine or pseudoephedrine exported from or transiting through the customs territory of the Union in order to prevent their diversion for the illicit manufacture of narcotic drugs or psychotropic substances.

(4) In its Conclusions of 25 May 2010 on the functioning and implementation of EU drug precursors legislation, the Council invited the Commission to propose legislative amendments after carefully assessing their potential impact on Member States' authorities and economic operators.

(5) This Regulation clarifies the definition of a scheduled substance: in this regard, the term 'pharmaceutical preparation', which stems from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988 ('the United Nations Convention'), is deleted as it is already covered by the relevant terminology of Union legal acts, namely 'medicinal products'. Moreover, the term 'other preparations' is deleted as it duplicates the term 'mixtures' already used in that definition.

(6) Rules on suspending or revoking the registration of an operator should be introduced in order to match the existing rules for suspending or revoking a licence.

(7) Medicinal products and veterinary medicinal products ('medicinal products') containing ephedrine or pseudoephedrine should be controlled without impeding their legitimate trade. To that end, a new category (Category 4) should be added to the Annex to Regulation (EC) No 111/2005 listing medicinal products containing certain scheduled substances.

(8) The export of medicinal products listed in Category 4 of the Annex to Regulation (EC) No 111/2005, as amended by this Regulation, should be preceded by an export authorisation, and a pre-export notification sent by the competent authorities in the Union to the competent authorities of the country of destination.

(9) Member States' competent authorities should be given the powers to stop or seize those medicinal products where there are reasonable grounds for suspecting that they are intended for the illicit manufacture of narcotic drugs or psychotropic substances, when they are exported, imported or in transit.

(10) With a view to enabling Member States to react more quickly with regard to new trends in drug precursors' diversion, their possibilities to act in cases of suspicious transactions involving non-scheduled substances should be clarified. To that end, Member States should be able to empower their competent authorities to obtain information on any orders for or operations involving non-scheduled substances, or to enter business premises to obtain evidence of suspicious transactions involving such substances. In addition, competent authorities should prevent the introduction into, or the departure from, the customs territory of the Union of non-scheduled substances, where it can be demonstrated

⁽¹⁾ Position of the European Parliament of 23 October 2013 (not yet published in the Official Journal) and decision of the Council of 15 November 2013.

⁽²⁾ Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).

that such substances will be used in the illicit manufacture of narcotic drugs or psychotropic substances. Such non-scheduled substances should be considered as proposed for inclusion in the voluntary monitoring list of non-scheduled substances.

(11) Member States' competent authorities should share between themselves and with the Commission, through the European database on drug precursors ('the European database'), established under Regulation (EC) No 273/2004 of the European Parliament and of the Council⁽¹⁾, information on seizures and stopped shipments in order to improve the overall level of information on trade in drug precursors, including medicinal products. The European database should be used to simplify the reporting by Member States with regard to seizures and stopped shipments. It should also serve as a European register of operators holding a licence or registration which will facilitate verification of the legitimacy of their transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances. That European register should be regularly updated and the information it contains should be used by the Commission and Member States' competent authorities only for the purpose of preventing the diversion of drug precursors onto the illegal market.

(12) Regulation (EC) No 111/2005 provides for the processing of data. Such processing may also cover personal data and should be carried out in accordance with Union law.

(13) The processing of personal data for the purposes of Regulation (EC) No 111/2005, as amended by this Regulation, and any delegated and implementing acts adopted pursuant thereto should respect the fundamental right to respect for private and family life recognised by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms as well as the right to respect for private and family life, and the right to the protection of personal data recognised, respectively, by Articles 7 and 8 of the Charter of Fundamental Rights of the European Union.

(14) Member States and the Commission should process personal data only in a manner compatible with the purposes of Regulation (EC) No 111/2005, as amended

by this Regulation, and the delegated and implementing acts adopted pursuant thereto. Those data should be processed in accordance with Union legislation concerning the protection of individuals with regard to the processing of personal data, in particular Directive 95/46/EC of the European Parliament and of the Council⁽²⁾ and Regulation (EC) No 45/2001 of the European Parliament and of the Council⁽³⁾.

(15) Regulation (EC) No 111/2005 confers powers on the Commission in order to implement some of its provisions, to be exercised in accordance with the procedures laid down in Council Decision 1999/468/EC⁽⁴⁾.

(16) As a consequence of the entry into force of the Treaty of Lisbon, those powers should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).

(17) In order to achieve the objectives of Regulation (EC) No 111/2005, as amended by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to set out the conditions for granting licences and registration and for determining cases where a licence or a registration is not required, to establish the criteria to determine how the licit purposes of the transaction may be demonstrated, to determine the information that is required by the competent authorities and by the Commission to allow them to monitor export, import or intermediary activities of operators, to determine the lists of the countries of destination to which exports of scheduled substances of Categories 2 and 3 of the Annex to Regulation (EC) No 111/2005 are to be preceded by a pre-export notification, to determine simplified pre-export notification procedures and to establish the common criteria to be applied by the competent authorities, to determine simplified export authorisation procedures and to establish the common criteria to be applied by the competent authorities, and to adapt the Annex to Regulation (EC) No 111/2005 in order to respond to new trends in diversion of drug precursors and to follow any amendment to the tables

⁽¹⁾ Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).

⁽²⁾ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

⁽³⁾ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

⁽⁴⁾ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

in the Annex to the United Nations Convention. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

- (18) In order to ensure uniform conditions for the implementation of Regulation (EC) No 111/2005, as amended by this Regulation, implementing powers should be conferred on the Commission, namely to establish a model for licences, the procedural rules on the provision of information that is required by the competent authorities to monitor export, import or intermediary activities of operators, and the measures to ensure the effective monitoring of trade between the Union and third countries in drug precursors, in particular with regard to the design and use of export and import authorisation forms, for the purpose of preventing the diversion of drug precursors. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (19) The delegated and implementing acts adopted pursuant to Regulation (EC) No 111/2005, as amended by this Regulation, should guarantee a systematic and consistent control and monitoring of operators.
- (20) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 18 January 2013 ⁽²⁾.
- (21) Regulation (EC) No 111/2005 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 111/2005 is amended as follows:

- (1) in the title of the Regulation and in Article 1, in points (d) and (e) of Article 2, in Article 10(1), in the first paragraph of Article 17, in the first paragraph of Article 20 and in Article 25, the noun 'Community' is replaced by the noun 'Union'. In point (e) of Article 2, in point (d) of

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

⁽²⁾ Not yet published in the Official Journal.

Article 13(1), in the first subparagraph of Article 14(1), in Article 14(2), in Article 18 and in the first paragraph of Article 22, the term 'Community customs territory' is replaced by the term 'customs territory of the Union'. In the first subparagraph of Article 12(1), the term 'Customs territory from the Community' is replaced by the term 'customs territory of the Union';

(2) in Article 2:

(a) point (a) is replaced by the following:

'(a) "scheduled substance" means any substance listed in the Annex that can be used for the illicit manufacture of narcotic drugs or psychotropic substances, including mixtures and natural products containing such substances, but excluding mixtures and natural products which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council (*) and veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council (**), except medicinal products and veterinary medicinal products listed in the Annex;

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

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

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

'(c) "import" means any entry of scheduled substances having the status of non-Union goods into the customs territory of the Union, including temporary storage, the placing in a free zone or free warehouse, the placing under a suspensive procedure and the release for free circulation within the meaning of Council Regulation (EEC) No 2913/92 (*);

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

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

‘(j) “natural product” means an organism or a part thereof, in any form, or any substances which occur in nature as defined in point 39 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (*);

(*) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).’;

(3) the first paragraph of Article 3 is replaced by the following:

‘All imports, exports or intermediary activities involving scheduled substances, with the exception of substances listed in Category 4 of the Annex, shall be documented by the operator by way of customs and commercial documents, such as summary declarations, customs declarations, invoices, cargo manifests, transport and other shipping documents.’;

(4) Article 5 is replaced by the following:

‘Article 5

Operators shall ensure that labels are affixed on any packaging containing scheduled substances, except substances listed in Category 4 of the Annex, indicating their name as stated in the Annex, or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, except substances listed in Category 4 of the Annex, as stated in the Annex, contained in the mixture or in the natural product. Operators may, in addition, affix their customary labels.’;

(5) in Article 6:

(a) paragraph 1 is replaced by the following:

‘1. Unless otherwise provided, operators established in the Union, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances listed in Category 1 of the

Annex, shall hold a licence. The competent authority of the Member State in which the operator is established shall issue the licence.

In considering whether to grant a licence, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to set out the conditions for granting licences and for determining cases where a licence is not required.’;

(b) the following paragraph is added:

‘3. The Commission shall establish a model for licences by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).’;

(6) Article 7 is replaced by the following:

‘Article 7

1. Unless otherwise provided, operators established in the Union, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances listed in Category 2 of the Annex, or in the export of scheduled substances listed in Category 3 of the Annex, shall hold a registration. The competent authority in the Member State in which the operator is established shall issue the registration.

In considering whether to grant a registration, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to set out the conditions for granting registrations and for determining cases where a registration is not required.

2. The competent authority may suspend or revoke the registration where the conditions under which the registration was issued are no longer fulfilled or where there are reasonable grounds for suspecting that there is a risk of diversion of scheduled substances.’;

(7) Article 8 is replaced by the following:

'Article 8

1. When the scheduled substances are entered into the customs territory of the Union for unloading or transhipment, for temporary storage, for their storage in a free zone of control type I or a free warehouse, or for their placing under the external Union transit procedure, the licit purposes must be demonstrated by the operator, upon request by the competent authorities.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to establish the criteria to determine how the licit purposes of the transaction may be demonstrated, in order to ensure that all movements of scheduled substances within the customs territory of the Union can be monitored by the competent authorities and the risk of diversion be minimised.'

(8) Article 9 is replaced by the following:

'Article 9

1. Operators established in the Union shall notify the competent authorities immediately of any circumstances, such as unusual orders and transactions involving scheduled substances, which suggest that such substances intended for import, export or intermediary activities might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances.

To that end, operators shall provide any available information, such as:

- (a) the name of the scheduled substance;
- (b) the quantity and weight of the scheduled substance;
- (c) the names and addresses of the exporter, the importer, the ultimate consignee and, where applicable, the person involved in the intermediary activities.

That information shall only be collected for the purposes of preventing the diversion of scheduled substances.

2. Operators shall provide the competent authorities with information in summary form about their export, import or intermediary activities.

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine the information that is required by the competent authorities in order to allow them to monitor those activities.

The Commission shall specify by means of implementing acts the procedural rules on the provision of such information, including, where appropriate, in electronic form to the European database on drug precursors established under Regulation (EC) No 273/2004 of the European Parliament and of the Council (*) ("the European database"). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).

(*) Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).';

(9) in Article 10, the following paragraphs are added:

'4. In order to respond rapidly to new diversion trends, the competent authorities of the Member States and the Commission may propose to add a non-scheduled substance to the list referred to in paragraph 2(b) in order to temporarily monitor its trade. Detailed arrangements and criteria for the inclusion or deletion from that list shall be specified in the guidelines referred to in paragraph 1.

5. If voluntary monitoring by the industry is considered insufficient to prevent the use of a non-scheduled substance for the illicit manufacture of narcotic drugs or psychotropic substances, the Commission may add the non-scheduled substance to the Annex by means of delegated acts in accordance with Article 30b.'

(10) in Article 11:

(a) in paragraph 1, the first subparagraph is replaced by the following:

'1. All exports of scheduled substances listed in Categories 1 and 4 of the Annex and exports of scheduled substances listed in Categories 2 and 3 of the Annex to certain countries of destination shall be preceded by a pre-export notification sent from the competent authorities in the Union to the competent authorities of the country of destination, in accordance with Article 12(10) of the United Nations Convention. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b of this Regulation to determine the lists of the countries of destination for export of scheduled substances listed in Categories 2 and 3 of the Annex in order to minimise the risk of diversion of scheduled substances.'

(b) paragraph 3 is replaced by the following:

‘3. Simplified pre-export notification procedures may be applied by the competent authorities where they are satisfied that this will not result in any risk of diversion of scheduled substances. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine such procedures and to establish the common criteria to be applied by the competent authorities.’;

(11) in Article 12(1), the third subparagraph is replaced by the following:

‘However, exports of scheduled substances listed in Category 3 of the Annex shall only be subject to an export authorisation where pre-export notifications are required.’;

(12) in Article 13(1), the following subparagraph is added:

‘An application for an export authorisation for exports of scheduled substances listed in Category 4 of the Annex shall contain the information set out in points (a) to (e) of the first subparagraph.’;

(13) Article 19 is replaced by the following:

Article 19

Simplified procedures to grant an export authorisation may be applied by the competent authorities where they are satisfied that this will not result in any risk of diversion of scheduled substances. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine such procedures and to establish the common criteria to be applied by the competent authorities.’;

(14) in Article 20, the second paragraph is replaced by the following:

‘However, where the substances referred to in the first paragraph are unloaded or transhipped, under temporary storage, stored in a free zone of control type I or a free warehouse, or placed under the external Union transit procedure, such import authorisation shall not be required.’;

(15) in Article 26:

(a) paragraph 1 is replaced by the following:

‘1. Without prejudice to Articles 11 to 25 and to paragraphs 2 and 3 of this Article, the competent authorities of each Member State shall prohibit the introduction of scheduled substances into the customs territory of the Union or their departure

from it, where there are reasonable grounds for suspecting that such substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.’;

(b) the following paragraphs are inserted:

‘3a. The competent authorities of each Member State shall prohibit the introduction of consignments of non-scheduled substances into the customs territory of the Union or their departure from it where there is sufficient evidence that those substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

The competent authority shall immediately inform the competent authorities of the other Member States and the Commission thereof, using the procedure referred to in Article 27.

Those substances shall be considered as proposed for inclusion in the list of non-scheduled substances referred to in point (b) of Article 10(2).

3b. Each Member State may adopt the measures necessary to enable its competent authorities to control and monitor suspicious transactions involving non-scheduled substances, in particular:

(a) to obtain information on any orders for or operations involving non-scheduled substances;

(b) to enter business premises in order to obtain evidence of suspicious transactions involving non-scheduled substances.’;

(16) the title of Chapter V is replaced by the following:

‘DELEGATED AND IMPLEMENTING ACTS’;

(17) Article 28 is replaced by the following:

Article 28

In addition to the measures referred to in Article 26, the Commission shall be empowered to lay down, where necessary, by means of implementing acts, measures to ensure the effective monitoring of trade between the Union and third countries in drug precursors, in particular with regard to the design and use of export and import authorisation forms, for the purpose of preventing the diversion of drug precursors. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).’;

(18) Article 29 is deleted;

(19) Article 30 is replaced by the following:

‘Article 30

1. The Commission shall be assisted by the Drug Precursors Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (*).

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

(*) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).;

(20) the following Articles are inserted:

‘Article 30a

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b of this Regulation in order to adapt the Annex hereto to new trends in diversion of drug precursors, in particular substances which can be easily transformed into scheduled substances, and to follow any amendment to the tables in the Annex to the United Nations Convention.

Article 30b

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in the third subparagraph of Article 6(1), the third subparagraph of Article 7(1), Article 8(2), the second subparagraph of Article 9(2), Article 10(5), Article 11(1) and (3), Articles 19 and 30a and Article 32(2) shall be conferred on the Commission for a period of five years from 30 December 2013. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in the third subparagraph of Article 6(1), the third subparagraph of Article 7(1), Article 8(2), the second subparagraph of

Article 9(2), Article 10(5), Article 11(1) and (3), Articles 19 and 30a and Article 32(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to the third subparagraph of Article 6(1), the third subparagraph of Article 7(1), Article 8(2), the second subparagraph of Article 9(2), Article 10(5), Article 11(1) and (3), Articles 19 and 30a and Article 32(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.;

(21) Article 32 is replaced by the following:

‘Article 32

1. The competent authorities in each Member State shall communicate to the Commission in electronic form via the European database in a timely manner all relevant information on the implementation of the monitoring measures laid down in this Regulation, in particular as regards substances used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture, and their licit trade.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b in order to specify the conditions and requirements concerning the information to be provided under paragraph 1 of this Article.

3. On the basis of the information referred to in paragraph 1 of this Article, the Commission shall, in consultation with the Member States, evaluate the effectiveness of this Regulation and, in accordance with Article 12(12) of the United Nations Convention, draw up an annual report to be submitted to the International Narcotics Control Board.

4. The Commission shall submit by 31 December 2019 a report to the European Parliament and to the Council on the implementation and functioning of this Regulation, and in particular on the possible need for additional action to monitor and control suspicious transactions with non-scheduled substances;

(22) the following Article is inserted:

‘Article 32a

The competent authorities of the Member States and the Commission shall use the European database under the conditions for its use for the following functions:

- (a) to facilitate the communication of information pursuant to Article 32(1) as well as the reporting to the International Narcotics Control Board pursuant to Article 32(3);
- (b) to manage a European register of operators, which have been granted a licence or registration;
- (c) to enable operators to provide the competent authorities with information about their export, import or intermediary activities according to Article 9(2), in electronic form.’;

(23) Article 33 is replaced by the following:

‘Article 33

1. The processing of personal data by the competent authorities in the Member States shall be carried out in accordance with national laws, regulations and administrative provisions transposing Directive 95/46/EC of the European Parliament and of the Council (*) and under the supervision of the supervisory authority of the Member State referred to in Article 28 of that Directive.

2. The processing of personal data by the Commission, including for the purpose of the European database, shall be carried out in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council (**) and under the supervision of the European Data Protection Supervisor.

3. No special categories of data within the meaning of Article 8(1) of Directive 95/46/EC shall be processed for the purposes of this Regulation.

4. The personal data collected for the purposes of this Regulation shall not be further processed in a way incon-

sistent with Directive 95/46/EC or Regulation (EC) No 45/2001 and shall not be retained longer than necessary for the purposes for which it was collected.

5. Member States and the Commission shall not process personal data in a manner incompatible with the purposes set out in Article 32a.

Without prejudice to Article 13 of Directive 95/46/EC, personal data obtained or processed pursuant to this Regulation shall be used for the purpose of preventing the diversion of scheduled substances.

(*) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

(**) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).’;

(24) in the Annex:

(a) the title is replaced by the following:

‘List of scheduled substances’;

(b) before the first table, the following subtitle is inserted:

‘Category 1’;

(c) in Category 1, the CN Code for Norephedrine is replaced by the following:

‘2939 44 00’;

(d) in Category 1, the following substance is added to the list of substances:

‘Alpha-phenylacetonitrile, CN Code 2926 90 95, CAS No 4468-48-8’;

(e) the following category is added:

‘Category 4

Substance	CN designation (if different)	CN Code
Medicinal products and veterinary medicinal products containing ephedrine or its salts	Containing ephedrine or its salts	3003 40 20 3004 40 20

Substance	CN designation (if different)	CN Code
Medicinal products and veterinary medicinal products containing pseudo- ephedrine or its salts	Containing pseudoep- hedrine (INN) or its salts	3003 40 30 3004 40 30’

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 Strasbourg, 20 November 2013.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
V. LEŠKEVIČIUS

REGULATION (EU) No 1260/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 November 2013
on European demographic statistics
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 338(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

- (1) According to Article 16(4) of the Treaty on European Union (TEU), as from 1 November 2014, a qualified majority of the members of the Council is to be defined, *inter alia*, on the basis of the population of the Member States.
- (2) The Economic and Financial Affairs Council regularly gives a mandate to the Economic Policy Committee to assess the long-term sustainability and quality of public finances on the basis of population projections produced by Eurostat.
- (3) In accordance with Regulation (EC) No 1059/2003 of the European Parliament and of the Council ⁽²⁾, all Member State statistics transmitted to the Commission which are broken down by territorial units are to use the NUTS classification. Consequently, in order to establish comparable regional statistics, the territorial units should be defined in accordance with the NUTS classification.
- (4) In accordance with the second paragraph of Article 175 of the Treaty on the Functioning of the European Union (TFEU), the Commission is to submit a report to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions

every three years on the progress made towards achieving economic, social and territorial cohesion. Annual regional data at NUTS 3 regional level is necessary for the preparation of those reports and for the regular monitoring of demographic developments and of possible future demographic challenges in the Union regions, including different types of regions such as border regions, metropolitan regions, rural regions and mountain and island regions. Since demographic ageing exhibits strong regional differences, Eurostat is required to prepare regional projections on a regular basis in order to complement the demographic picture of the NUTS 2 regions in the Union.

- (5) In accordance with Article 159 TFEU, the Commission is to draw up a report each year on progress in achieving the objectives of Article 151 TFEU, including the demographic situation in the Union.
- (6) The Commission in its Communication of 20 October 2009 entitled 'Solidarity in health: reducing health inequalities in the EU' supported the further development and collection of data, and the further development of health indicators, by age, sex, socioeconomic status and geographic dimensions.
- (7) The Sustainable Development Strategy of the Union, launched by the European Council in Gothenburg in 2001 and renewed in June 2006, has as its objective the continuous improvement of the quality of life for current and future generations. The Commission (Eurostat) monitoring report, which is published every two years, provides an objective statistical picture of progress, based on a Union set of sustainable development indicators.
- (8) Annual demographic statistics are fundamental for the study and definition of a wide range of policies, with particular regard to social and economic issues, at national and regional level. Statistics on population are an important denominator for a wide range of policy indicators.
- (9) The strategic objective H.3. of Chapter IV of the Beijing Platform for Action (1995) provides a reference framework for the generation and dissemination of gender-disaggregated data and information for planning and policy evaluation reasons.

⁽¹⁾ Position of the European Parliament of 22 October 2013 (not yet published in the Official Journal) and decision of the Council of 15 November 2013.

⁽²⁾ Regulation (EC) No 1059/2003 of the European Parliament and of the Council of 26 May 2003 on the establishment of a common classification of territorial units for statistics (NUTS) (OJ L 154, 21.6.2003, p. 1).

- (10) Demographic statistics constitute an essential component for the estimation of total population in the framework of the European System of Accounts. It is important to update and revise data when establishing statistics at European level.
- (11) In order to ensure the quality, and in particular the comparability, of the data provided by the Member States, and in order for reliable overviews to be drawn up at Union level, the data used should be based on the same concepts, and should refer to the same reference date or period.
- (12) Regulation (EC) No 223/2009 of the European Parliament and of the Council⁽¹⁾ provides a reference framework for European demographic statistics. In particular, it requires compliance with the principles of professional independence, impartiality, objectivity, reliability, statistical confidentiality and cost effectiveness.
- (13) The information on demography should be consistent with the relevant information collected pursuant to Regulation (EC) No 862/2007 of the European Parliament and of the Council⁽²⁾ and Regulation (EC) No 763/2008 of the European Parliament and of the Council⁽³⁾. To this end, scientifically-based and well-documented statistical estimation methods should be evaluated, and their use should be encouraged.
- (14) When developing, producing and disseminating European statistics, the national and European statistical authorities, and, where applicable, other relevant national and regional authorities, should take account of the principles set out in the European Statistics Code of Practice, as reviewed and updated by the European Statistical System Committee on 28 September 2011.
- (15) This Regulation guarantees the right to respect for private and family life and to the protection of personal data, as set out in Articles 7 and 8 of the Charter of Fundamental Rights of the European Union.
- (16) Directive 95/46/EC of the European Parliament and of the Council⁽⁴⁾ and Regulation (EC) No 45/2001 of the European Parliament and of the Council⁽⁵⁾ apply with regard to the processing of personal data in the context of this Regulation.
- (17) Since the objective of this Regulation, namely the establishment of a common legal framework for the systematic production of European demographic statistics in the Member States, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve that objective.
- (18) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽⁶⁾,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes a common legal framework for the development, production and dissemination of European statistics on population and vital events.

Article 2

Definitions

For the purpose of this Regulation, the following definitions apply:

- (a) 'national' refers to the territory of a Member State within the meaning of Regulation (EC) No 1059/2003 applicable at the reference time;

⁽¹⁾ Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).

⁽²⁾ Regulation (EC) No 862/2007 of the European Parliament and of the Council of 11 July 2007 on Community statistics on migration and international protection and repealing Council Regulation (EEC) No 311/76 on the compilation of statistics on foreign workers (OJ L 199, 31.7.2007, p. 23).

⁽³⁾ Regulation (EC) No 763/2008 of the European Parliament and of the Council of 9 July 2008 on population and housing censuses (OJ L 218, 13.8.2008, p. 14).

⁽⁴⁾ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

⁽⁵⁾ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

⁽⁶⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (b) 'regional' means NUTS level 1, NUTS level 2 or NUTS level 3 within the meaning of Regulation (EC) No 1059/2003 applicable at the reference time; where this term is used in connection with countries that are not members of the Union, 'regional' means the statistical regions at level 1, 2 or 3, as agreed between those countries and the Commission (Eurostat), at the reference time;
- (c) 'usually resident population' means all persons having their usual residence in a Member State at the reference time;
- (d) 'usual residence' means the place where a person normally spends the daily period of rest, regardless of temporary absences for purposes of recreation, holidays, visits to friends and relatives, business, medical treatment or religious pilgrimage. The following persons alone shall be considered to be usual residents of a specific geographical area:
- (i) those who have lived in their place of usual residence for a continuous period of at least 12 months before the reference time; or
 - (ii) those who arrived in their place of usual residence during the 12 months before the reference time with the intention of staying there for at least one year.

Where the circumstances described in point (i) or (ii) cannot be established, 'usual residence' can be taken to mean the place of legal or registered residence, except for the purposes of Article 4.

In applying the definition of 'usual residence', Member States shall treat special cases in accordance with the Annex to Commission Regulation (EC) No 1201/2009 ⁽¹⁾;

- (e) 'live birth' means the birth of a child who breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles, regardless of gestational age;
- (f) 'death' means the permanent disappearance of all evidence of life at any time after live birth has taken place (post-natal cessation of vital functions without capability of resuscitation);
- (g) 'vital events' means live births and deaths as defined in points (e) and (f).

Article 3

Data on population and on vital events

1. Member States shall provide the Commission (Eurostat) with data on their usually resident population at the reference

time. The data provided shall cover population by age, sex and region of residence.

2. Member States shall provide the Commission (Eurostat) with data on their vital events that occurred during the reference period. Member States shall use the same population definition that they use for the data referred to in paragraph 1. The data provided shall cover the following variables:

- (a) live births by sex, month of occurrence, live birth-order, mother's age, mother's year of birth, mother's country of birth, mother's country of citizenship and mother's region of residence;
- (b) deaths by age, sex, year of birth, region of residence, country of birth, country of citizenship and month of occurrence.

3. Member States shall use the same definition of population for all 'national' and 'regional' levels as defined by this Regulation.

4. The Commission shall adopt implementing acts laying down uniform conditions for the breakdown of data referred to in paragraphs 1 and 2, for deadlines and for revisions of data. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 10(2).

Article 4

Total population for specific Union purposes

1. For the purposes of qualified majority voting in the Council, Member States shall provide the Commission (Eurostat) with data on the total population at national level at the reference time, in accordance with Article 2(c), within eight months of the end of the reference year.

2. Member States may estimate the total population referred to in paragraph 1 from the legally resident or registered population using scientifically-based, well-documented, and publicly available statistical estimation methods.

Article 5

Frequency and reference time

1. Each year, Member States shall provide the Commission (Eurostat) with data on their population and on their vital events for the previous year referred to in Article 3(1) and in points (a) and (b) of Article 3(2).

2. Each year Member States shall provide the Commission (Eurostat) with data on the total population at national level referred to in Article 4.

⁽¹⁾ Commission Regulation (EC) No 1201/2009 of 30 November 2009 implementing Regulation (EC) No 763/2008 of the European Parliament and of the Council on population and housing censuses as regards the technical specifications of the topics and of their breakdowns (OJ L 329, 15.12.2009, p. 29).

3. For the purposes of this Regulation, the reference time shall mean either the reference date referred to in paragraph 4 or the reference period referred to in paragraph 5, as appropriate.

4. The reference date for population data shall be the end of the reference period (midnight of 31 December). The first reference date shall be in 2013 and the last reference date shall be in 2027.

5. The reference period for vital events data shall be the calendar year in which the events occurred. The first reference period shall be 2013 and the last reference period shall be 2027.

Article 6

Provision of data and metadata

Member States shall make available to the Commission (Eurostat) the data and metadata required under this Regulation in accordance with the data and metadata exchange standards specified by the Commission (Eurostat). Member States shall either provide those data and metadata through the Single Entry Point services so that the Commission (Eurostat) can retrieve them, or shall transmit them using the Single Entry Point services.

Article 7

Data sources

The data shall be based on the data sources chosen by the Member State in accordance with national law and practice. Scientifically-based and well-documented statistical estimation methods shall be used, where appropriate.

Article 8

Feasibility studies

1. Member States shall carry out feasibility studies on the use of the definition of 'usual residence' for population and vital events as referred to in Article 3(1) and (2).

2. The results of the feasibility studies referred to in paragraph 1 shall be transmitted to the Commission by 31 December 2016.

3. In order to facilitate the carrying out of the feasibility studies referred to in paragraph 1 of this Article, the Union may provide financial support to the national statistical institutes and other national authorities referred to in Article 5 of Regulation (EC) No 223/2009.

Article 9

Quality requirements

1. Member States shall ensure the quality of the data transmitted.

2. For the purposes of this Regulation, the quality criteria referred to in Article 12(1) of Regulation (EC) No 223/2009 shall apply to the data to be transmitted.

3. Member States shall report to the Commission (Eurostat) on reference metadata, using the European Statistical System standards, and in particular on the data sources, definitions and estimation methods used for the first reference year, and Member States shall keep the Commission (Eurostat) informed of any changes thereto.

4. At the request of the Commission (Eurostat), Member States shall provide it with all the information necessary to evaluate the quality of the statistical information.

5. Member States shall ensure that the data on population required by Article 3 of this Regulation are consistent with those required by point (c) of Article 3(1) of Regulation (EC) No 862/2007.

Article 10

Committee procedure

1. The Commission shall be assisted by the European Statistical System Committee established by Regulation (EC) No 223/2009. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 11

Review Clause

1. The Commission shall submit a first report to the European Parliament and to the Council on the implementation of this Regulation by 31 December 2018, and a second report by 31 December 2023. In those reports, the Commission shall take account of relevant information provided by Member States and shall evaluate the quality of the data transmitted, the data collection methods used, the additional burden imposed on the Member States and on the respondents, and the comparability of those statistics. Those reports shall evaluate the use of scientifically-based, well-documented statistical estimation methods, for the estimation of the 'usually resident population' from the legally resident or registered population. The first report shall also cover the results of the feasibility studies referred to in Article 8.

2. If appropriate, those reports shall be accompanied by proposals designed to further improve the common legal framework for the development, production and dissemination of European statistics on population and vital events under this Regulation.

*Article 12***Entry into force**

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

This Regulation shall cease to apply on 31 August 2028.

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

Done at Strasbourg, 20 November 2013.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

V. LEŠKEVIČIUS

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