



2025/928

31.7.2025

COMMISSION DELEGATED REGULATION (EU) 2025/928

of 21 May 2025

amending Regulation (EU) 2019/125 of the European Parliament and of the Council concerning trade in certain goods which could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/125 of the European Parliament and of the Council of 16 January 2019 concerning trade in certain goods which could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment ⁽¹⁾, and in particular the first paragraph of Article 24 thereof,

Whereas:

- (1) Pursuant to Regulation (EU) 2019/125 any export, import, transit of goods listed in Annex II shall be prohibited, irrespective of the origin of such goods. Annex II comprises goods which have no practical use other than for the purpose of capital punishment or for the purpose of torture and other cruel, inhuman or degrading treatment or punishment.
- (2) Pursuant to Regulation (EU) 2019/125 for any export of goods listed in Annex III, an authorisation shall be required, irrespective of the origin of such goods. Annex III comprises the goods that could be used for the purpose of torture or other cruel, inhuman or degrading treatment or punishment, namely goods which are primarily used for law enforcement purposes, and goods which, taking into account their design and technical features, present a material risk of use for torture or other cruel, inhuman or degrading treatment or punishment.
- (3) The list of goods set out in Annexes II and III to Regulation (EU) 2019/125 needs to stay updated in order to respond to changes in the international security market where technological and market developments are occurring frequently and to changes in the use, and misuse, of law enforcement equipment. Annexes II and III to Regulation (EU) 2019/125 should therefore be amended. In order to facilitate references for the competent authorities and economic operators, Annexes II and III to that Regulation should be replaced.
- (4) Article 24 of Regulation (EU) 2019/125 empowers the Commission to adopt delegated acts in accordance with Article 29, to amend the Annexes to the Regulation.
- (5) Regulation (EU) 2019/125 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) 2019/125 is replaced by the text in the Annex I to this Regulation.

Annex III to Regulation (EU) 2019/125 is replaced by the text in the Annex II to this Regulation.

⁽¹⁾ OJ L 30, 31.1.2019, p. 1, , ELI: <http://data.europa.eu/eli/reg/2019/125/oj>.

Article 2

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

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

Done at Brussels, 21 May 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

ANNEX II

LIST OF GOODS REFERRED TO IN ARTICLES 3 AND 4

Introductory Notes:

The “CN codes” in this Annex refer to codes specified in Part Two of Annex I to Council Regulation (EEC) No 2658/87 ⁽¹⁾.

Where “ex” precedes the CN code, the goods covered by this Regulation constitute only a part of the scope of the CN code and are determined by both the description given in this Annex and the scope of the CN code.

Notes:

- Items 1.3 and 1.4 in Section 1 concerning goods designed for the execution of human beings do not cover medical-technical goods.
- The object of the controls contained in this Annex should not be defeated by the export of any non-controlled goods (including plants) containing one or more controlled components when the controlled component or components are the principal element of the goods and can feasibly be removed or used for other purposes.

NB: In judging whether the controlled component or components are to be considered the principal element, it is necessary to weigh the factors of quantity, value and technological know-how involved and other special circumstances which might establish the controlled component or components as the principal element of the goods being procured.

| CN code | Description |
|--|--|
| | 1. Goods designed for the execution of human beings, as follows: |
| ex 4421 99 ex 8208 90 00 | 1.1. Gallows, guillotines, and blades for guillotines |
| ex 8543 70 90 ex 9401 79 00 ex 9401 80 00 ex 9402 10 00 | 1.2. Electric chairs for the purpose of execution of human beings |
| ex 9406 20 00 ex 9406 90 38 ex 9406 90 90 | 1.3. Airtight vaults, made of e.g., steel and glass, designed for the purpose of execution of human beings by the administration of a lethal gas or substance. |
| ex 8413 81 00 ex 9018 90 50 ex 9018 90 60 ex 9018 90 84 | 1.4. Automatic drug injection systems designed for the purpose of execution of human beings by the administration of a lethal chemical substance |
| | 2. Goods which are not suitable for use by law enforcement authorities to restrain human beings, as follows: |
| ex 8543 70 90 | 2.1. Electric shock devices which are intended to be worn on the body by a restrained individual, such as belts, sleeves, and cuffs, designed for restraining human beings by the administration of electric shocks. |

⁽¹⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1, ELI: <http://data.europa.eu/eli/reg/1987/2658/oj>).

| CN code | Description |
|---|--|
| ex 7326 90 98 ex 7616 99 90 ex 8301 50 00 ex 3926 90 97 ex 4203 30 00 ex 4203 40 00 ex 4205 00 90 ex 4017 00 00 | 2.2. Thumb-cuffs, finger-cuffs, thumbscrews, and finger-screws. <i>Note:</i> This item includes both serrated and non-serrated cuffs and screws. |
| ex 7326 90 98 ex 7616 99 90 ex 8301 50 00 ex 3926 90 97 ex 4203 30 00 ex 4203 40 00 ex 4205 00 90 ex 6217 10 00 ex 6307 90 98 ex 4017 00 00 | 2.3. Bar fetters, weighted leg restraints and gang chains comprising bar fetters or weighted leg restraints. <i>Notes:</i> 1. Bar fetters are shackles or ankle rings fitted with a locking mechanism, linked by a rigid bar which is typically made of metal. 2. This item includes bar fetters and weighted leg restraints which are linked to ordinary handcuff by means of a chain. |
| ex 7326 90 98 ex 7616 99 90 ex 8301 50 00 ex 3926 90 97 ex 4203 30 00 ex 4203 40 00 ex 4205 00 90 ex 6217 10 00 ex 6307 90 98 ex 7315 81 00 ex 7315 82 00 ex 7315 89 00 ex 4017 00 00 | 2.4. Gang chains <i>Note:</i> Gang chains comprise multiple pairs of handcuffs, leg cuffs, belly chains, or a combination of these, attached to a single chain (often made of metal), restraining several people together in a chain. |
| ex 7326 90 98 ex 7616 99 90 ex 7315 81 00 ex 7315 82 00 ex 7315 89 00 | 2.5. Leg irons <i>Note:</i> Leg irons are non-adjustable metal rings or other non-adjustable metal restraints that are fixed around a prisoner's ankles, normally by means of a bolt or screw arrangement. They can be hinged or unhinged and are normally linked with a chain. (They are distinct from leg cuffs which can be adjusted on a detainee's ankle (Annex III, 1.3)). |
| ex 7326 90 98 ex 7616 99 90 ex 8301 50 00 ex 3926 90 97 ex 4203 30 00 ex 4203 40 00 ex 4205 00 90 ex 6217 10 00 ex 6307 90 98 ex 4017 00 00 | 2.6. Cuffs for restraining human beings, designed to be anchored to a wall, floor or ceiling |
| ex 9401 61 00 ex 9401 69 00 ex 9401 71 00 ex 9401 79 00 ex 9401 80 00 ex 9402 10 00 | 2.7. Restraint chairs: chairs fitted with shackles or other devices to restrain a human being. <i>Note:</i> This item does not prohibit chairs only fitted with straps or belts |
| ex 9402 90 00 ex 9403 20 80 ex 9403 50 00 ex 9403 60 00 ex 9403 89 00 | 2.8. Shackle boards and shackle beds: boards and beds fitted with shackles or other devices to restrain a human being. <i>Note:</i> This item does not prohibit boards and beds only fitted with straps or belts |

| CN code | Description |
|---|--|
| ex 9402 90 00 ex 9403 50 00 ex 9403 60 00 ex 9403 70 00 ex 9403 89 00 | 2.9. Cage beds: beds comprising a cage (four sides and a ceiling) or similar structure enclosing a human being within the confines of the bed, the ceiling or one or more of the sides of which are fitted with metal or other bars, and which can only be opened from outside |
| ex 9402 90 00 ex 9403 20 20 ex 9403 50 00 ex 9403 60 90 ex 9403 70 00 ex 9403 89 00 | 2.10. Net beds: beds comprising a cage (four sides and a ceiling) or similar structure enclosing a human being within the confines of the bed, the ceiling or one or more sides of which are fitted with nets, and which can only be opened from outside |
| ex 6505 00 10 ex 6505 00 90 ex 6506 91 00 ex 6506 99 10 ex 6506 99 90 ex 6217 10 00 ex 6307 90 98 | 2.11. Hoods and blindfolds solely designed for law enforcement purposes to block the vision and/or enclose the face of a person/detainee, including such hoods and blindfolds when linked by a chain to ordinary handcuffs or other restraints. <i>Note:</i> This item does not include spit hoods which are controlled in Annex III 1.4. |
| | 3. Portable devices which are not suitable for use by law enforcement authorities for the purpose of riot control or self-protection, as follows: |
| ex 9304 00 00 | 3.1. Batons or truncheons made of metal or other material having a shaft with metal spikes |
| ex 7326 90 98 ex 4205 00 90 ex 6602 00 00 ex 7326 90 98 ex 7806 00 80 ex 4203 29 90 ex 4015 19 00 | 3.2. Weighted batons or batons encased in thick leather or rubber with additional weighting designed to increase kinetic impact to the target and weighted gloves or other similar devices <i>Notes:</i> 1. Weighted baton: A flat device consisting of metal (spring steel) encased in thick leather or rubber and used for slapping or striking a person; or a short baton consisting of spring steel encased in leather, sometimes weighted at one end with lead shot, and used for striking a person. 2. Weighted gloves are usually made of leather and have powdered steel or lead sewn into the material over the knuckle, fingers, or back of the hand. |
| ex 4421 91 00 ex 4421 99 99 ex 3926 90 97 ex 6602 00 00 | 3.3. Lathis <i>Note:</i> Lathis are long flexible batons (over 1m long), traditionally made of wood or bamboo but also polycarbonate of the kind used as a weapon by police officers. |
| ex 3926 90 97 ex 7326 90 98 | 3.4. Shields with metal spikes |
| ex 3926 20 00 ex 7326 90 98 ex 7616 99 90 ex 4017 00 00 | 3.5. Body armour with spikes or serrations made of metal or other hard material. <i>Note:</i> This item does not control body armours with load-bearing systems featuring parts made of metal or other hard material used to attach or carry equipment. |
| | 4. Whips as follows: |
| ex 6602 00 00 | 4.1. Whips comprising multiple lashes or thongs, such as knouts or cats o'nine tails. |
| ex 6602 00 00 | 4.2. Whips having one or more lashes or thongs fitted with barbs, hooks, spikes, metal wire or similar objects enhancing the impact of the lash or thong. |

| CN code | Description |
|---|--|
| ex 6602 00 00 | <p>4.3. "Sjamboks"</p> <p><i>Note:</i> This item alludes to a type of heavy whip, traditionally made of leather, or of other materials, such as plastic. This item does not cover instruments traditionally used for herding animals.</p> |
| | <p>5. Weapons and equipment disseminating incapacitating or irritating chemicals or impact projectiles and related ammunition which are not suitable for use by law enforcement authorities for the purpose of riot control or self-protection.</p> |
| ex 8424 20 00 ex 8424 89 70 ex 9304 00 00 | <p>5.1. Fixed equipment for the dissemination of incapacitating or irritating chemical substances in enclosed spaces, which can be attached to a wall or to a ceiling inside a building, comprises a canister of irritating or incapacitating chemical agents and is activated using a remote-control system.</p> <p><i>Note:</i> This item alludes to equipment or devices of the kind used in prisons and other places of detention. It does not prohibit fixed equipment designed for the dissemination of blinding substances (such as water vapour or fog), that do not cause direct physical harm, used in commercial or private enclosed spaces for the purpose of burglary prevention.</p> |
| ex 9301 10 00 ex 9301 20 00 ex 9301 90 00 ex 9302 00 00 ex 9303 10 00 ex 9303 20 10 ex 9303 20 95 ex 9303 30 00 ex 9303 90 00 ex 9304 00 00 ex 9306 21 00 ex 9306 29 00 ex 9306 30 10 ex 9306 30 30 ex 9306 30 90 ex 9306 90 10 ex 9306 90 90 | <p>5.2. Equipment and explosive projectiles for dispensing injurious quantities of riot control agents from aerial platforms.</p> <p><i>Note:</i> This item does not control smoke grenades and does not control aerial platforms as such. This item includes equipment where the mode of dispersal is inherently inaccurate, or the equipment or projectiles are able to disperse amounts of riot control agent that are injurious.'</p> |

ANNEX II

ANNEX III

LIST OF GOODS REFERRED TO IN ARTICLE 11

Introductory Notes:

The CN codes in this Annex refer to codes specified in Part Two of Annex I to Regulation (EEC) No 2658/87.

Where “ex” precedes the CN code, the goods covered by this Regulation constitute only a part of the scope of the CN code and are determined by both the description given in this Annex and the scope of the CN code.

Notes:

1. The object of the controls contained in this Annex should not be defeated by the export of any non-controlled goods (including plant) containing one or more controlled components when the controlled component or components are the principal element of the goods and can feasibly be removed or used for other purposes.

NB: In judging whether the controlled component or components are to be considered the principal element, it is necessary to weigh the factors of quantity, value and technological know-how involved and other special circumstances which might establish the controlled component or components as the principal element of the goods being procured.

2. In some instances, chemicals are listed by name and CAS number. The list applies to chemicals of the same structural formula (including hydrates) regardless of name or CAS number. CAS numbers are shown to assist in identifying a particular chemical or mixture, irrespective of nomenclature. CAS numbers cannot be used as unique identifiers because some forms of the listed chemical have different CAS numbers, and mixtures containing a listed chemical may also have different CAS numbers.

| CN code | Description |
|---|---|
| | 1. Goods designed for restraining human beings, as follows: |
| ex 7326 90 98 ex 7616 99 90 ex 8301 50 00 ex 3926 90 97 ex 4203 30 00 ex 4203 40 00 ex 4205 00 90 ex 6217 10 00 ex 6307 90 98 ex 7315 81 00 ex 7315 82 00 ex 7315 89 00 ex 4017 00 00 | 1.1. Shackles <i>Notes:</i> 1. Shackles are restraints consisting of two cuffs or rings fitted with a locking mechanism, with a connecting chain or bar. 2. This item does not control the leg restraints and gang chains prohibited by item 2.3 and 2.4 of Annex II. 3. This item does not control “ordinary handcuffs”. Ordinary handcuffs are handcuffs which meet all the following conditions: — their overall dimension including chain, measured from the outer edge of one cuff to the outer edge of the other cuff, is between 150 and 280 mm when both cuffs are locked; — the inside circumference of each cuff is a maximum of 165 mm when the ratchet is engaged at the last notch entering the locking mechanism; — the inside circumference of each cuff is a minimum of 200 mm when the ratchet is engaged at the first notch entering the locking mechanism; and — the cuffs have not been modified to cause physical pain or suffering. |

| CN code | Description |
|---|--|
| ex 7326 90 98 ex 7616 99 90 ex 8301 50 00 ex 3926 90 97 ex 4203 30 00 ex 4203 40 00 ex 4205 00 90 ex 6217 10 00 ex 6307 90 98 ex 4017 00 00 | 1.2. Individual cuffs or rings fitted with a locking mechanism, having an inside circumference exceeding 165 mm when the ratchet is engaged at the last notch entering the locking mechanism. <i>Note:</i> This item includes neck restraints and other individual cuffs or rings fitted with a locking mechanism, which are linked to ordinary handcuffs by means of a chain. |
| ex 7326 90 98 ex 7616 99 90 ex 8301 50 00 ex 3926 90 97 ex 4203 30 00 ex 4203 40 00 ex 4205 00 90 ex 6217 10 00 ex 6307 90 98 ex 7315 81 00 ex 7315 82 00 ex 7315 89 00 ex 4017 00 00 | 1.3. Leg cuffs <i>Notes:</i> 1. Leg cuffs are restraints consisting of two cuffs, usually made of metal, fastened around the ankles, and attached by a chain to allow the detainee some movement. The cuff size is usually larger than those ordinary handcuffs and is adjustable. 2. This item does not control leg restraints and gang chains prohibited by items 2.3, 2.4, 2.5 and 2.6 of Annex II. |
| ex 6505 00 10 ex 6505 00 90 ex 6506 91 00 ex 6506 99 10 ex 6506 99 90 | 1.4. Spit hoods: hoods, including hoods made of netting, comprising a cover of the mouth which prevents spitting. <i>Note:</i> This item includes spit hoods which are linked to ordinary handcuffs by means of a chain. |
| | 2. Weapons and devices designed for the purpose of law enforcement including riot control or self-protection, as follows: |
| ex 8543 70 90 ex 9304 00 00 | 2.1. Portable electric discharge weapons that can target only one individual each time an electric shock is administered, including but not limited to electric shock batons, electric shock shields, stun guns and electric shock dart guns <i>Notes:</i> 1. This item does not control electric shock belts and other devices falling within item 2.1 of Annex II. 2. This item does not control individual electronic shock devices when accompanying their user for the user's own personal protection. |
| ex 8543 90 00 ex 9305 99 00 | 2.2. Kits containing all essential components for assembly of portable electric discharge weapons controlled by item 2.1. <i>Note:</i> The following goods are considered to be essential components: — the unit producing an electric shock, — the switch, whether or not on a remote control, and — the electrodes or, where applicable, the wires through which the electrical shock is to be administered. |
| ex 8543 70 90 ex 9304 00 00 | 2.3. Fixed or mountable electric discharge weapons that cover a wide area and can target multiple individuals with electrical shocks |
| ex 9303 90 00 ex 9304 00 00 ex 9306 30 90 ex 9306 90 90 | 2.4. Single shot kinetic impact projectile (KIP) launchers and associated kinetic impact projectiles <i>Note:</i> This item includes projectiles commonly known as rubber or plastic bullets or impact rounds, chemical irritant impact projectiles and beanbags. They come in different shapes and sizes include large and small balls or cylinders, and can be made of rubber, PVC, dense foam, or wood. This item does not control equipment controlled by items ML1, 2 and 12 of the Common Military List of the European Union. |

| CN code | Description |
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| ex 9301 10 00 ex 9301 20 00 ex 9301 90 00 ex 9302 00 00 ex 9303 10 00 ex 9303 20 10 ex 9303 20 95 ex 9303 30 00 ex 9303 90 00 ex 9304 00 00 | 2.5. Launchers and dissemination devices including multiple barrel launchers <i>Note:</i> This item includes multiple-barrel launchers that typically have between 2 and 36 barrels, and can be stand-alone or mounted onto vehicles, unmanned ground vehicles, or seafaring vessels. The launchers can be manually operated or operated by remote control, allowing for individual, sequential, or simultaneous firing of kinetic impact munitions or chemical irritants, resulting in rapid fire or bursts of fire. This item does not control equipment controlled by items ML1 and ML 2 of the Common Military List of the European Union. |
| ex 9306 21 00 ex 9306 29 00 ex 9306 30 10 ex 9306 30 30 ex 9306 30 90 ex 9306 90 10 ex 9306 90 90 | 2.6. Ammunition containing multiple kinetic impact projectiles <i>Note:</i> This item includes ammunition that can be made from rubber, plastic, or wood, and can vary in terms of their size, number, and shape. The number included in each can range from a small number of large balls or blocks to hundreds of small pellets. This item does not control equipment controlled by items ML1 and ML 2 of the Common Military List of the European Union. |
| | 3. Weapons and equipment disseminating incapacitating or irritating chemicals for use by law enforcement authorities for the purpose of riot control or self-protection, as follows: |
| ex 8424 20 00 ex 8424 89 70 ex 9304 00 00 | 3.1. Portable weapons and equipment which either administer a dose of an incapacitating or irritating chemical substance that targets one individual or disseminate a dose of such substance affecting a small area, e.g. in the form of a spray fog or cloud, when the chemical substance is administered or disseminated. <i>Notes:</i> 1. This item does not control equipment controlled by item ML7(e) of the Common Military List of the European Union ⁽¹⁾ . 2. This item does not control individual portable equipment, even if containing a chemical substance, when accompanying their user for the user's own personal protection. 3. In addition to relevant chemical substances, such as riot control agents or PAVA, the goods controlled by items 3.3, 3.4 and 3.7 shall be deemed to be incapacitating or irritating chemical substances. |
| ex 2939 79 90 | 3.2. Pelargonic acid vanillylamide (PAVA) (CAS RN 2444-46-4) <i>Note:</i> This item does not control equipment controlled by item ML7(e) of the Common Military List of the European Union. |
| ex 3301 90 30 ex 1302 19 70 | 3.3. Oleoresin capsicum (OC) (CAS RN 8023-77-6) <i>Note:</i> This item does not control equipment controlled by item ML7(e) of the Common Military List of the European Union. |
| ex 3301 90 30 ex 3302 10 90 ex 3302 90 10 ex 3302 90 90 ex 3824 99 92 | 3.4. Mixtures containing at least 0,3 % by weight of PAVA or OC and a solvent (such as ethanol, 1-propanol or hexane), which could be administered as such as incapacitating or irritating agents, in particular in aerosols and in liquid form, or used for manufacturing of incapacitating or irritating agents <i>Notes:</i> 1. This item does not control sauces and preparations therefor, soups or preparations therefor and mixed condiments or seasonings, provided that PAVA or OC is not the only constituent flavour in them. 2. This item does not control medicinal products for which a marketing authorisation has been granted in accordance with Union law ⁽²⁾ |

| CN code | Description |
|--|--|
| ex 8424 20 00 ex 8424 89 70 ex 9304 00 00 | <p>3.5. Fixed or mountable equipment for the dissemination of incapacitating or irritating chemical agents that covers a wide area and is not designed to be attached to a wall or to a ceiling inside a building.</p> <p>Notes:</p> <ol style="list-style-type: none"> 1. This item does not control equipment controlled by item ML7(e) of the Common Military List of the European Union. 2. This item also controls water cannons. 3. In addition to relevant chemical substances, such as riot control agents or PAVA, the goods controlled by items 3.3 and 3.4 shall be deemed to be incapacitating or irritating chemical substances. |
| ex 9306 21 00 ex 9306 29 00 ex 9306 30 10 ex 9306 30 30 ex 9306 30 90 ex 9306 90 10 ex 9306 90 90 | <p>3.6. Large calibre projectiles containing riot control agents.</p> <p>Note:</p> <p>This item includes projectiles containing riot control agents, notably OC and PAVA with a calibre above 56mm. The use of such items must be consistent with relevant provisions of the Chemical Weapons Convention, notably Article 2.1 and 2.9.d.</p> |
| ex 2934 99 90 ex 2930 90 95 ex 2933 99 20 ex 2921 29 00 ex 2830 90 85 ex 3824 99 92 ex 3824 99 93 ex 3824 99 96 | <p>3.7. Malodorant chemical mixtures formulated to produce a foul and deeply unpleasant smell for riot control purposes provided they are non-injurious and have no long-lasting health effects.</p> <p>Notes:</p> <ol style="list-style-type: none"> 1. This item is defined as being a mixture solely designed for law enforcement purposes containing at least one of the following range of chemicals formulated to produce a foul and deeply unpleasant smell and that can be dispersed by hand-held spray, grenades, launched projectiles, drones, and water cannon: <ol style="list-style-type: none"> 1. Thioacetone (CAS code 4756-05-2) 2. Allicin (CAS code 539-86-6) 3. Skatole (CAS code 83-34-1) 4. Cadaverine (CAS code 462-94-2) 5. Putrescine (CAS code 110-60-1) 6. Ammonium hydrosulfide (CAS code 12124-99-1) 7. Ethanethiol (CAS code 75-08-1) 8. Propanethiol (CAS code 107-03-9) 9. Isobutylthiol (CAS code 513-44-0) 10. Butanethiol (CAS code 109-79-5) 2. This item does not control malodorant chemical mixtures that are not intended for law enforcement purposes. |

(¹) Last version adopted by the Council on 19 February 2024 (OJ C, C/2024/1945, 1.3.2024, ELI: <http://data.europa.eu/eli/C/2024/1945/oj>).

(²) See in particular Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: <http://data.europa.eu/eli/reg/2004/726/oj>) and 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, <http://data.europa.eu/eli/dir/2001/83/oj>).