

ANNEX

Part I

- A. Point (a)(i) of Article 2(1) — public procurement:
1. Rules of procedure for public procurement and the award of concessions, for the award of contracts in the fields of defence and security, and for the award of contracts by entities operating in the fields of water, energy, transport and postal services and any other contract, as set out in:
 - (i) Directive 2014/23/EU of the European Parliament and of the Council of 26 February 2014 on the award of concession contracts ([OJ L 94, 28.3.2014, p. 1](#));
 - (ii) Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC ([OJ L 94, 28.3.2014, p. 65](#));
 - (iii) Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC ([OJ L 94, 28.3.2014, p. 243](#));
 - (iv) Directive 2009/81/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security, and amending Directives 2004/17/EC and 2004/18/EC ([OJ L 216, 20.8.2009, p. 76](#)).
 2. Review procedures regulated by:
 - (i) Council Directive 92/13/EEC of 25 February 1992 coordinating the laws, regulations and administrative provisions relating to the application of Community rules on the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors ([OJ L 76, 23.3.1992, p. 14](#));
 - (ii) Council Directive 89/665/EEC of 21 December 1989 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts ([OJ L 395, 30.12.1989, p. 33](#)).
- B. Point (a)(ii) of Article 2(1) — financial services, products and markets, and prevention of money laundering and terrorist financing:

Rules establishing a regulatory and supervisory framework and consumer and investor protection in the Union's financial services and capital markets, banking, credit, investment, insurance and re-insurance, occupational or personal pensions products, securities, investment funds, payment services and the activities listed in Annex I to Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC ([OJ L 176, 27.6.2013, p. 338](#)), as set out in:

- (i) Directive 2009/110/EC of the European Parliament and of the Council of 16 September 2009 on the taking up, pursuit and prudential supervision of the business of electronic money institutions amending Directives 2005/60/EC and 2006/48/EC and repealing Directive 2000/46/EC ([OJ L 267, 10.10.2009, p. 7](#));

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- (ii) Directive 2011/61/EU of the European Parliament and of the Council of 8 June 2011 on Alternative Investment Fund Managers and amending Directives 2003/41/EC and 2009/65/EC and Regulations (EC) No 1060/2009 and (EU) No 1095/2010 ([OJ L 174, 1.7.2011, p. 1](#));
- (iii) Regulation (EU) No 236/2012 of the European Parliament and of the Council of 14 March 2012 on short selling and certain aspects of credit default swaps ([OJ L 86, 24.3.2012, p. 1](#));
- (iv) Regulation (EU) No 345/2013 of the European Parliament and of the Council of 17 April 2013 on European venture capital funds ([OJ L 115, 25.4.2013, p. 1](#));
- (v) Regulation (EU) No 346/2013 of the European Parliament and of the Council of 17 April 2013 on European social entrepreneurship fund ([OJ L 115, 25.4.2013, p. 18](#));
- (vi) Directive 2014/17/EU of the European Parliament and of the Council of 4 February 2014 on credit agreements for consumers relating to residential immovable property and amending Directives 2008/48/EC and 2013/36/EU and Regulation (EU) No 1093/2010 ([OJ L 60, 28.2.2014, p. 34](#));
- (vii) Regulation (EU) No 537/2014 of the European Parliament and of the Council of 16 April 2014 on specific requirements regarding statutory audit of public-interest entities and repealing Commission Decision 2005/909/EC ([OJ L 158, 27.5.2014, p. 77](#));
- (viii) Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012 ([OJ L 173, 12.6.2014, p. 84](#));
- (ix) Directive (EU) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC ([OJ L 337, 23.12.2015, p. 35](#));
- (x) Directive 2004/25/EC of the European Parliament and of the Council of 21 April 2004 on takeover bids ([OJ L 142, 30.4.2004, p. 12](#));
- (xi) Directive 2007/36/EC of the European Parliament and of the Council of 11 July 2007 on the exercise of certain rights of shareholders in listed companies ([OJ L 184, 14.7.2007, p. 17](#));
- (xii) Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004 on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC ([OJ L 390, 31.12.2004, p. 38](#));
- (xiii) Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories ([OJ L 201, 27.7.2012, p. 1](#));
- (xiv) Regulation (EU) 2016/1011 of the European Parliament and of the Council of 8 June 2016 on indices used as benchmarks in financial instruments and financial contracts or to measure the performance of investment funds and amending Directives 2008/48/EC and 2014/17/EU and Regulation (EU) No 596/2014 ([OJ L 171, 29.6.2016, p. 1](#));
- (xv) Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) ([OJ L 335, 17.12.2009, p. 1](#));

- (xvi) Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council ([OJ L 173, 12.6.2014, p. 190](#));
 - (xvii) Directive 2002/87/EC of the European Parliament and of the Council of 16 December 2002 on the supplementary supervision of credit institutions, insurance undertakings and investment firms in a financial conglomerate and amending Council Directives 73/239/EEC, 79/267/EEC, 92/49/EEC, 92/96/EEC, 93/6/EEC and 93/22/EEC, and Directives 98/78/EC and 2000/12/EC of the European Parliament and of the Council ([OJ L 35, 11.2.2003, p. 1](#));
 - (xviii) Directive 2014/49/EU of the European Parliament and of the Council of 16 April 2014 on deposit guarantee schemes ([OJ L 173, 12.6.2014, p. 149](#));
 - (xix) Directive 97/9/EC of the European Parliament and of the Council of 3 March 1997 on investor-compensation schemes ([OJ L 84, 26.3.1997, p. 22](#));
 - (xx) Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 ([OJ L 176, 27.6.2013, p. 1](#)).
- C. Point (a)(iii) of Article 2(1) — product safety and compliance:
- 1. Safety and compliance requirements for products placed in the Union market, as defined and regulated by:
 - (i) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety ([OJ L 11, 15.1.2002, p. 4](#));
 - (ii) Union harmonisation legislation concerning manufactured products, including labelling requirements, other than food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction as listed in Annexes I and II to Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 ([OJ L 169, 25.6.2019, p. 1](#));
 - (iii) Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) ([OJ L 263, 9.10.2007, p. 1](#)).
 - 2. Rules on marketing and use of sensitive and dangerous products, as set out in:
 - (i) Directive 2009/43/EC of the European Parliament and of the Council of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community ([OJ L 146, 10.6.2009, p. 1](#));
 - (ii) Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons ([OJ L 256, 13.9.1991, p. 51](#));

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- (iii) Regulation (EU) No 98/2013 of the European Parliament and the Council of 15 January 2013 on the marketing and use of explosives precursors ([OJ L 39, 9.2.2013, p. 1](#)).
- D. Point (a)(iv) of Article 2(1) — transport safety:
 - 1. Safety requirements in the railway sector, as regulated by Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety ([OJ L 138, 26.5.2016, p. 102](#)).
 - 2. Safety requirements in the civil aviation sector, as regulated by Regulation (EU) No 996/2010 of the European Parliament and of the Council of 20 October 2010 on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC ([OJ L 295, 12.11.2010, p. 35](#)).
 - 3. Safety requirements in the road sector, as regulated by:
 - (i) Directive 2008/96/EC of the European Parliament and of the Council of 19 November 2008 on road infrastructure safety management ([OJ L 319, 29.11.2008, p. 59](#));
 - (ii) Directive 2004/54/EC of the European Parliament and of the Council of 29 April 2004 on minimum safety requirements for tunnels in the Trans-European Road Network ([OJ L 167, 30.4.2004, p. 39](#));
 - (iii) Regulation (EC) No 1071/2009 of the European Parliament and of the Council of 21 October 2009 establishing common rules concerning the conditions to be complied with to pursue the occupation of road transport operator and repealing Council Directive 96/26/EC ([OJ L 300, 14.11.2009, p. 51](#)).
 - 4. Safety requirements in the maritime sector, as regulated by:
 - (i) 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](#));
 - (ii) Regulation (EC) No 392/2009 of the European Parliament and of the Council of 23 April 2009 on the liability of carriers of passengers by sea in the event of accidents ([OJ L 131, 28.5.2009, p. 24](#));
 - (iii) Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC ([OJ L 257, 28.8.2014, p. 146](#));
 - (iv) Directive 2009/18/EC of the European Parliament and of the Council of 23 April 2009 establishing the fundamental principles governing the investigation of accidents in the maritime transport sector and amending Council Directive 1999/35/EC and Directive 2002/59/EC ([OJ L 131, 28.5.2009, p. 114](#));
 - (v) Directive 2008/106/EC of the European Parliament and of the Council of 19 November 2008 on the minimum level of training of seafarers ([OJ L 323, 3.12.2008, p. 33](#));
 - (vi) Council Directive 98/41/EC of 18 June 1998 on the registration of persons sailing on board passenger ships operating to or from ports of the Member States of the Community ([OJ L 188, 2.7.1998, p. 35](#));

- (vii) Directive 2001/96/EC of the European Parliament and of the Council of 4 December 2001 establishing harmonised requirements and procedures for the safe loading and unloading of bulk carriers (OJ L 13, 16.1.2002, p. 9).
- 5. Safety requirements, as regulated by Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).
- E. Point (a)(v) of Article 2(1) — protection of the environment:
 - 1. Any criminal offence against the protection of the environment as regulated by 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) or any unlawful conduct infringing the legislation set out in the Annexes to Directive 2008/99/EC;
 - 2. Rules on the environment and climate, as set out in:
 - (i) Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC (OJ L 275, 25.10.2003, p. 32);
 - (ii) Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16);
 - (iii) Directive 2012/27/EU of the European Parliament and of the Council of 25 October 2012 on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing Directives 2004/8/EC and 2006/32/EC (OJ L 315, 14.11.2012, p. 1);
 - (iv) Regulation (EU) No 525/2013 of the European Parliament and of the Council of 21 May 2013 on a mechanism for monitoring and reporting greenhouse gas emissions and for reporting other information at national and Union level relevant to climate change and repealing Decision No 280/2004/EC (OJ L 165, 18.6.2013, p. 13);
 - (v) Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (OJ L 328, 21.12.2018, p. 82).
 - 3. Rules on sustainable development and waste management, as set out in:
 - (i) 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);
 - (ii) 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);
 - (iii) Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p. 60).
 - 4. Rules on marine, air and noise pollution, as set out in:
 - (i) Directive 1999/94/EC of the European Parliament and of the Council of 13 December 1999 relating to the availability of consumer information on fuel economy and CO₂

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- emissions in respect of the marketing of new passenger cars ([OJ L 12, 18.1.2000, p. 16](#));
- (ii) Directive 2001/81/EC of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants ([OJ L 309, 27.11.2001, p. 22](#));
 - (iii) Directive 2002/49/EC of the European Parliament and of the Council of 25 June 2002 relating to the assessment and management of environmental noise ([OJ L 189, 18.7.2002, p. 12](#));
 - (iv) Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships ([OJ L 115, 9.5.2003, p. 1](#));
 - (v) Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage ([OJ L 143, 30.4.2004, p. 56](#));
 - (vi) Directive 2005/35/EC of the European Parliament and of the Council of 7 September 2005 on ship-source pollution and on the introduction of penalties for infringements ([OJ L 255, 30.9.2005, p. 11](#));
 - (vii) Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC ([OJ L 33, 4.2.2006, p. 1](#));
 - (viii) Directive 2009/33/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of clean and energy-efficient road transport vehicles ([OJ L 120, 15.5.2009, p. 5](#));
 - (ix) Regulation (EC) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO₂ emissions from light-duty vehicles ([OJ L 140, 5.6.2009, p. 1](#));
 - (x) Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer ([OJ L 286, 31.10.2009, p. 1](#));
 - (xi) Directive 2009/126/EC of the European Parliament and of the Council of 21 October 2009 on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations ([OJ L 285, 31.10.2009, p. 36](#));
 - (xii) Regulation (EU) No 510/2011 of the European Parliament and of the Council of 11 May 2011 setting emission performance standards for new light commercial vehicles as part of the Union's integrated approach to reduce CO₂ emissions from light-duty vehicles ([OJ L 145, 31.5.2011, p. 1](#));
 - (xiii) Directive 2014/94/EU of the European Parliament and of the Council of 22 October 2014 on the deployment of alternative fuels infrastructure ([OJ L 307, 28.10.2014, p. 1](#));
 - (xiv) Regulation (EU) 2015/757 of the European Parliament and of the Council of 29 April 2015 on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport, and amending Directive 2009/16/EC ([OJ L 123, 19.5.2015, p. 55](#));

- (xv) Directive (EU) 2015/2193 of the European Parliament and of the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants ([OJ L 313, 28.11.2015, p. 1](#)).
5. Rules on the protection and management of water and soil, as set out in:
- (i) Directive 2007/60/EC of the European Parliament and of the Council of 23 October 2007 on the assessment and management of flood risks ([OJ L 288, 6.11.2007, p. 27](#));
- (ii) Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council ([OJ L 348, 24.12.2008, p. 84](#));
- (iii) Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment ([OJ L 26, 28.1.2012, p. 1](#)).
6. Rules relating to the protection of nature and biodiversity, as set out in:
- (i) Council Regulation (EC) No 1936/2001 of 27 September 2001 laying down control measures applicable to fishing for certain stocks of highly migratory fish ([OJ L 263, 3.10.2001, p. 1](#));
- (ii) Council Regulation (EC) No 812/2004 of 26 April 2004 laying down measures concerning bycatches of cetaceans in fisheries and amending Regulation (EC) No 88/98 ([OJ L 150, 30.4.2004, p. 12](#));
- (iii) Regulation (EC) No 1007/2009 of the European Parliament and of the Council of 16 September 2009 on trade in seal products ([OJ L 286, 31.10.2009, p. 36](#));
- (iv) Council Regulation (EC) No 734/2008 of 15 July 2008 on the protection of vulnerable marine ecosystems in the high seas from the adverse impacts of bottom fishing gears ([OJ L 201, 30.7.2008, p. 8](#));
- (v) Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds ([OJ L 20, 26.1.2010, p. 7](#));
- (vi) Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market ([OJ L 295, 12.11.2010, p. 23](#));
- (vii) Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species ([OJ L 317, 4.11.2014, p. 35](#)).
7. Rules on chemicals, as set out in 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](#)).
8. Rules relating to organic products, as set out in Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and

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labelling of organic products and repealing Council Regulation (EC) No 834/2007 ([OJ L 150, 14.6.2018, p. 1](#)).

F. Point (a)(vi) of Article 2(1) — radiation protection and nuclear safety

Rules on nuclear safety, as set out in:

- (i) Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations ([OJ L 172, 2.7.2009, p. 18](#));
- (ii) Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption ([OJ L 296, 7.11.2013, p. 12](#));
- (iii) Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom ([OJ L 13, 17.1.2014, p. 1](#));
- (iv) Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste ([OJ L 199, 2.8.2011, p. 48](#));
- (v) Council Directive 2006/117/Euratom of 20 November 2006 on the supervision and control of shipments of radioactive waste and spent fuel ([OJ L 337, 5.12.2006, p. 21](#));
- (vi) Council Regulation (Euratom) 2016/52 of 15 January 2016 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, and repealing Regulation (Euratom) No 3954/87 and Commission Regulations (Euratom) No 944/89 and (Euratom) No 770/90 ([OJ L 13, 20.1.2016, p. 2](#));
- (vii) Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States ([OJ L 148, 19.6.1993, p. 1](#)).

G. Point (a)(vii) of Article 2(1) — food and feed safety, animal health and animal welfare:

1. Union food and feed law governed by the general principles and requirements as defined by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([OJ L 31, 1.2.2002, p. 1](#)).
2. Animal health, as regulated by:
 - (i) Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ([OJ L 84, 31.3.2016, p. 1](#));
 - (ii) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) ([OJ L 300, 14.11.2009, p. 1](#)).
3. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No

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396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([OJ L 95, 7.4.2017, p. 1](#)).

4. Rules and standards on the protection and well-being of animals, as set out in:
- (i) Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes ([OJ L 221, 8.8.1998, p. 23](#));
 - (ii) Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 ([OJ L 3, 5.1.2005, p. 1](#));
 - (iii) Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing ([OJ L 303, 18.11.2009, p. 1](#));
 - (iv) Council Directive 1999/22/EC of 29 March 1999 relating to the keeping of wild animals in zoos ([OJ L 94, 9.4.1999, p. 24](#));
 - (v) Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes ([OJ L 276, 20.10.2010, p. 33](#)).
- H. Point (a) (viii) of Article 2(1) — public health:
- 1. Measures setting high standards of quality and safety of organs and substances of human origin, as regulated by:
 - (i) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC ([OJ L 33, 8.2.2003, p. 30](#));
 - (ii) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells ([OJ L 102, 7.4.2004, p. 48](#));
 - (iii) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation ([OJ L 207, 6.8.2010, p. 14](#)).
 - 2. Measures setting high standards of quality and safety for medicinal products and devices of medical use, as regulated by:
 - (i) Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products ([OJ L 18, 22.1.2000, p. 1](#));
 - (ii) 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](#));

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- (iii) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43);
 - (iv) 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);
 - (v) Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1);
 - (vi) Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121);
 - (vii) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).
3. Patients' rights, as regulated by Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).
 4. Manufacture, presentation and sale of tobacco and related products, as regulated by Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1).
- I. Point (a)(ix) of Article 2(1) — consumer protection:
- Consumer rights and consumer protection, as regulated by:
- (i) Directive 98/6/EC of the European Parliament and of the Council of 16 February 1998 on consumer protection in the indication of the prices of products offered to consumers (OJ L 80, 18.3.1998, p. 27);
 - (ii) Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and digital services (OJ L 136, 22.5.2019, p. 1);
 - (iii) Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC (OJ L 136, 22.5.2019, p. 28);
 - (iv) Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees (OJ L 171, 7.7.1999, p. 12);
 - (v) Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the distance marketing of consumer financial services and amending Council Directive 90/619/EEC and Directives 97/7/EC and 98/27/EC (OJ L 271, 9.10.2002, p. 16);

- (vi) Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive') ([OJ L 149, 11.6.2005, p. 22](#));
- (vii) Directive 2008/48/EC of the European Parliament and of the Council of 23 April 2008 on credit agreements for consumers and repealing Council Directive 87/102/EEC ([OJ L 133, 22.5.2008, p. 66](#));
- (viii) Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council ([OJ L 304, 22.11.2011, p. 64](#));
- (ix) Directive 2014/92/EU of the European Parliament and of the Council of 23 July 2014 on the comparability of fees related to payment accounts, payment account switching and access to payment accounts with basic features ([OJ L 257, 28.8.2014, p. 214](#)).
- J. Point (a)(x) of Article 2(1) — protection of privacy and personal data, and security of network and information systems:
 - (i) Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) ([OJ L 201, 31.7.2002, p. 37](#));
 - (ii) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) ([OJ L 119, 4.5.2016, p. 1](#));
 - (iii) Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union ([OJ L 194, 19.7.2016, p. 1](#)).