



Potential reports

Active or passive conduct may be reported, consisting of:

1. unlawful conduct relevant to the Decree or violations of the Model – general section, special sections, their annexes, Code of Ethics and procedures referred to in the Model itself, if adopted;
2. unlawful acts falling within the scope of European Union or national legislation in the following areas:

- **Public procurement:**

a) procedural rules for the award of public contracts and concessions, for the award of contracts in the defence and security sectors, as well as for the award of contracts by entities operating in the water, energy, transport and postal services sectors and any other contract;

b) appeal procedures for redressing Community infringements in the field of procurement and supply;

- **Financial services, products and markets, and prevention of money laundering and terrorist financing:**

a) rules establishing a regulatory and supervisory framework and providing for consumer and investor protection in the Union's financial services and capital markets and in the banking, credit, investment, insurance and reinsurance, occupational pensions or individual pension 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), implemented by Legislative Decree

12 May 2015, No. 72, implementing Directive 2013/36/EU, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC, as regards access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms. Amendments to Legislative Decree No. 385 of 1 September 1993 and Legislative Decree No. 58 of 24 February 1998, referred to in:

(i) Legislative Decree No. 45 of 16 April 2012, implementing Directive 2009/110/EC on the taking up, the exercise and prudential supervision of the activities of electronic money institutions, amending Directives 2005/60/EC and 2006/48/EC and repealing Directive 2000/46/EC;

(ii) Legislative Decree No. 44 of 4 March 2014, implementing Directive 2011/61/EU on alternative investment fund managers, amending Directives 2003/41/EC and 2009/65/EC and Regulations (EC) No. 1060/2009 and (EU) No 1095/2010;

(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 funds (OJ L 115, 25.4.2013, p. 18);

(vi) Legislative Decree No 72 of 21 April 2016 implementing Directive 2014/17/EU on credit agreements for consumers relating to residential immovable property and amending and supplementing Title VI-bis of Legislative Decree No 385 of 1 September 1993 on the regulation of financial agents and credit intermediaries and Legislative Decree No. 141 of 13 August 2010 (OJ L 60 of 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) Legislative Decree No 218 of 15 December 2017, transposing Directive (EU) 2015/2366 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, as well as adapting internal provisions to Regulation (EU) No. 751/2015 on interchange fees for card-based payment transactions;

(x) Legislative Decree No. 229 of 19 November 2007, implementing Directive 2004/25/EC on takeover bids;

(xi) Legislative Decree No. 27 of 27 January 2010, implementing Directive 2007/36/EC on the exercise of certain rights of shareholders in listed companies;

(xii) Legislative Decree No. 195 of 6 November 2007, implementing Directive 2004/109/EC 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; 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);

(xiii) 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 and on measures to protect against market manipulation and market abuse and amending Directives 2008/48/EC and 2014/17/EU and Regulation (EU) No 596/2014 (OJ L 171, 29.6.2016, p. 1);

(xiv) Legislative Decree No 74 of 12 May 2015 implementing Directive 2009/138/EC on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II);

(xv) Legislative Decree No. 180 of 16 November 2015, implementing Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for

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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; Legislative Decree No. 181 of 16 November 2015, amending Legislative Decree No. 385 of 1 September 1993 and Legislative Decree No. 58 of 24 February 1998, implementing 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;

(xvi) Legislative Decree No. 142 of 30 May 2005, implementing Directive 2002/87/EC on the supplementary supervision of credit institutions, insurance undertakings and investment firms in a financial conglomerate and the institution of prior consultation on insurance matters;

(xvii) Legislative Decree No. 30 of 15 February 2016, implementing Directive 2014/49/EU of the European Parliament and of the Council of 16 April 2014 on deposit guarantee schemes;

(xviii) Legislative Decree No. 415 of 23 July 1996, implementing Directive 93/22/EEC of 10 May 1993 on investment services in the securities sector and Directive 93/6/EEC of 15 March 1993 on the capital adequacy of investment firms and credit institutions; Decree of the Ministry of the Treasury, Budget and Economic Planning of 30 June 1998, published in the Official Gazette, No. 191, 18 August 1998, approving the statutes and operating regulations of the National Guarantee Fund for the protection of claims by clients against securities brokerage firms and other entities authorised to carry out securities brokerage activities; Decree of the Ministry of the Treasury, Budget and Economic Planning No. 485 of 14 November 1997, published in the Official Gazette No. 13, 17 January 1998, governing the organisation and operation of the compensation schemes referred to in Article 35(2) of Legislative Decree No. 415 of 23 July 1996, which transposed Directive 93/22/EEC on investment services in the securities sector;

(xix) 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); (xxi) Regulation (EU) 2020/1503 of the European Parliament and of the Council of 7 October 2020 on European business crowdfunding service providers and amending Regulation (EU) 2017/1129 and Directive (EU) 2019/1937 (OJ L 347, 20.10.2020, p. 1).

• **Product safety and compliance:**

a) safety and compliance requirements for products placed on the Union market, defined and regulated by the following acts:

(i) Legislative Decree No 206 of 6 September 2005, containing the Consumer Code, pursuant to Article 7 of Law No 229 of 29 July 2003 No. 229;

(ii) European Union harmonisation legislation relating to manufactured products, including labelling requirements, other than food, feed, medicinal products for human and veterinary use, live plants and animals, products of human origin and products of plants and animals directly related to their future reproduction, listed in Annexes I and II to Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and product compliance, 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).

b) regulations on the marketing and use of sensitive and dangerous products, referred to in:

(i) Legislative Decree No 105 of 22 June 2012, amending and supplementing Law No 185 of 9 July 1990, laying down new rules on the control of the export, import and transit of armaments, implementing Directive 2009/43/EC, which simplifies the terms and conditions for intra-Community transfers of defence-related products, as amended by Directives 2010/80/EU and 2012/10/EU with regard to the list of defence-related products.

• **Transport safety:**

a) Legislative Decree No. 50 of 14 May 2019, implementing Directive 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety.

b) 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).

c) Safety requirements in the road sector, governed by the following acts:

(i) Legislative Decree No 35 of 15 March 2011 implementing Directive 2008/96/EC on road infrastructure safety management;

(ii) Legislative Decree No 264 of 5 October 2006, implementing Directive 2004/54/EEC on safety requirements for tunnels in the Trans-European Road Network;

(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);

d) safety requirements in the maritime sector, governed by the following acts:

(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);

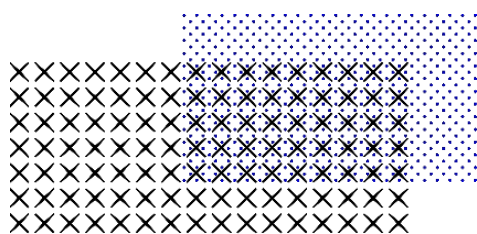
(iii) Decree of the President of the Republic of 20 December 2017, No 239, implementing Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Directive 96/98/EC;

(iv) Legislative Decree No. 165 of 6 September 2011, implementing Directive 2009/18/EC establishing the fundamental principles governing the investigation of accidents in the maritime transport sector and amending Directives 1999/35/EC and 2002/59/EC;

(v) Decree of the Minister of Transport and Navigation of 13 October 1999, published in the Official Gazette No. 251 of 25 October 1991, implementing 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;

(vi) Decree of the Minister of Infrastructure and Transport of 16 December 2004, published in the Official Gazette No. 43 of 22 February 2005, implementing Directive 2001/96/EC on 'Harmonised requirements and procedures for the safe loading and unloading of bulk carriers'.

e) Safety requirements governed by Legislative Decree No 35 of 27 January 2010, implementing Directive 2008/68/EC on the inland transport of dangerous goods.



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• **Environmental protection:**

a) any type of offence against environmental protection governed by Legislative Decree No. 121 of 7 July 2011, implementing Directive 2008/99/EC on the protection of the environment through criminal law, as well as Directive 2009/123/EC amending Directive 2005/35/EC on ship-source pollution and the introduction of penalties for infringements, or any offence that constitutes a violation of the legislation referred to in the annexes to Directive 2008/99/EC.

b) environmental and climate regulations, referred to in:

(i) Legislative Decree No. 30 of 13 March 2013, implementing Directive 2009/29/EC amending Directive 2003/87/EC in order to improve and extend the Community greenhouse gas emission allowance trading system;

(ii) Legislative Decree No. 102 of 4 July 2014, implementing Directive 2012/27/EU on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing those Directives;

(iii) Legislative Decree No. 199 of 8 November 2021, implementing 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.

c) regulations on sustainable development and waste management, referred to in:

(i) Legislative Decree No. 205 of 3 December 2010, implementing Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives;

(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 dangerous chemicals (OJ L 201, 27.7.2012, p. 60);

(iv) Legislative Decree No 28 of 10 February 2017, laying down penalties for infringements of the provisions of Regulation (EU) No 649/2012 on the export and import of dangerous chemicals.

d) regulations on marine, atmospheric and noise pollution, referred to in:

(i) Decree of the President of the Republic No. 84 of 17 February 2003, implementing Directive 1999/94/EC on the availability of consumer information on fuel economy and CO₂ emissions in respect of the marketing of new passenger cars;

(ii) Legislative Decree No. 194 of 19 August 2005, implementing Directive 2002/49/EC relating to the assessment and management of environmental noise;

(iii) 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);

(iv) Legislative Decree No 152 of 3 April 2006 laying down environmental regulations;

(v) Legislative Decree No 202 of 6 November 2007 implementing Directive 2005/35/EC on ship-source pollution and subsequent penalties;

(vi) 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);

(vii) 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);

(viii) Legislative Decree No 125 of 30 July 2012 implementing Directive 2009/126/EC on Stage II petrol vapour recovery during the refuelling of motor vehicles at service stations;

(ix) Legislative Decree No 257 of 16 December 2016, implementing Directive 2014/94/EU of the European Parliament and of the Council of 22 October 2014 on the deployment of alternative fuels infrastructure () and implementing Directive 2014/94/EU of the European Parliament and of the Council of 22 October 2014 on the deployment of alternative fuels infrastructure () (

European Parliament and of the Council of 22 October 2014 on the deployment of alternative fuels infrastructure;

(x) 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);

(xi) Legislative Decree No 183 of 15 November 2017 implementing 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, as well as for the reorganisation of the regulatory framework for establishments that produce emissions into the air, pursuant to Article 17 of Law No 170 of 12 August 2016.

e) regulations on water and soil protection and management, referred to in:

(i) Legislative Decree No. 49 of 23 February 2010, implementing Directive 2007/60/EC on the assessment and management of flood risks;

(ii) Legislative Decree No. 219 of 10 December 2010, implementing Directive 2008/105/EC on environmental quality standards in the field of water policy, amending and subsequently repealing Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC, and amending Directive 2000/60/EC and transposing Directive 2009/90/EC establishing, in accordance with Directive 2000/60/EC, technical specifications for chemical analysis and monitoring of water status;

(iii) Article 15, Decree-Law No. 91 of 24 June 2014, containing urgent provisions for the agricultural sector, environmental protection and energy efficiency in school and university buildings, the relaunch and development of businesses, the containment of costs affecting electricity tariffs, as well as for the immediate definition of obligations arising from European legislation; Decree of the Minister of the Environment and Protection of Land and Sea of 30 March 2015, published in Official Gazette No. 84, 11 April 2015, containing guidelines for verifying the subjection to environmental impact assessment of projects falling within the competence of the regions and autonomous provinces, as provided for in Article 15 of Decree-Law No. 91 of 24 June 2014, converted, with amendments, by Law No. 116 of 11 August 2014.

f) regulations on the protection of nature and biodiversity, referred to in:

(i) Council Regulation (EC) No 1936/2001 of 27 September 2001 laying down certain control measures applicable to fishing for certain stocks of highly migratory fish (OJ L 263, 3.10.2001, p. 1);

(ii) 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);

(iii) 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);

(iv) Article 42 of Law No 96 of 4 June 2010 laying down provisions for the fulfilment of obligations arising from Italy's membership of the European Communities – Community Law 2009;

(v) 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);

(vi) 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); Legislative Decree No 230 of 15 December 2017, adapting national legislation to the provisions of 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.

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g) regulations on chemical substances, referred to in:

(i) 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);

(ii) the authorisation and restriction of chemicals Legislative Decree No 133 of 14 September 2009, laying down penalties for infringements of the provisions of Regulation (EC) No 1907/2006 laying down the principles and requirements for the registration, evaluation;

(iii) Decree of the Minister of Health of 22 November 2007, published in the Official Gazette No. 12 of 15 January 2008, containing the plan of activities and use of financial resources referred to in Article 5-bis of Decree-Law No. 10 of 15 February 2007, No. 10, converted into law, with amendments, by Law No. 46 of 6 April 2007,

No. 46, concerning the requirements laid down in Regulation (EC)

No. 1907/2006 of the Parliament.

h) regulations on organic products, referred to in:

(i) Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

▪ **Radiation protection and nuclear safety:**

a) nuclear safety standards referred to in:

(i) Legislative Decree No 185 of 19 October 2011 implementing Directive 2009/71/EURATOM establishing a Community framework for the safety of nuclear installations;

(ii) Legislative Decree No 28 of 15 February 2016, implementing 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;

(iii) Legislative Decree No. 101 of 31 July 2020, implementing Directive 2013/59/EURATOM, 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/E

EURATOM and 2003/122/EURATOM and reorganising the sectoral legislation in implementation of Article 20, paragraph 1, letter a) of Law No. 117 of 4 October 2019;

(iv) Legislative Decree No. 45 of 4 March 2014, implementing Directive 2011/70/EURATOM, establishing a Community framework for the responsible and safe management of spent nuclear fuel and radioactive waste;

(v) Legislative Decree No. 23 of 20 February 2009, implementing Directive 2006/117/EURATOM on the supervision and control of shipments of radioactive waste and spent nuclear fuel;

(vi) Council Regulation (EURATOM) No 2016/52 of 15 January 2016 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency and repealing Council Regulation (EURATOM) No 3954/87 and Regulations (EURATOM) No 944/89 and (EURATOM) No 770/90 of the Commission (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).

▪ **Food and feed safety, animal health and welfare:**

a) Union rules on food and feed referred to in:

(i) 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).

b) animal health governed by the following acts:

(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); Legislative Decree No 134 of 5 August 2022 laying down provisions on the system for the identification and registration of operators, establishments and animals; Legislative Decree No 135 of 5 August 2022, laying down provisions implementing Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on trade, import, keeping of wild and exotic animals and training for animal operators and professionals, also with a view to reducing the risk of zoonotic outbreaks, as well as the introduction of criminal law provisions to punish illegal trade in protected species, pursuant to Article 14(2)(a), (b), (n), (o), (p) and (q) of Law No 53 of 22 April 2021;

No. 53; Legislative Decree No. 136 of 5 August 2022, implementing Article 14, paragraph 2, letters a), b), e), f), h), i), l), n), o) and p) of Law No. 53 of 22 April 2021, to adapt and align national legislation on the prevention and control of animal diseases that are transmissible to animals or humans with the provisions of Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016;

(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 (Regulation on animal by-products) (OJ L300 of 14.11.2009, p. 1); Legislative Decree No 186 of 1 October 2012 laying down penalties for infringements of Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002, and for violations of the provisions of Regulation (EU) No 142/2011 laying down implementing rules for Regulation (EC) No 1069/2009 and Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border;

(iii) 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, animal health and animal welfare rules, plant health rules and rules on plant protection products.

c) Rules on animal protection and welfare, including:

(i) Legislative Decree No 146 of 26 March 2001 implementing Directive 98/58/EC concerning the protection of animals kept for farming purposes;

(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); Legislative Decree No 151 of 25 July 2007 laying down penalties for infringements of Regulation (EC) No 1/2005 on the protection of animals during transport and related operations;

(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); Legislative Decree No 131 of 6 November 2013, laying down penalties for infringements of the provisions of Regulation (EC) No 1099/2009 on the protection of animals at the time of killing;

(iv) Legislative Decree No 73 of 21 March 2005 implementing Directive 1999/22/EC on the keeping of wild animals in zoos;

(v) Legislative Decree No. 26 of 4 March 2014, implementing Directive 2010/63/EU on the protection of animals used for scientific purposes.

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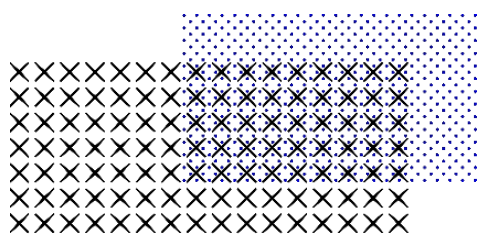
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▪ **Public health**

a) measures establishing high standards of quality and safety for organs and substances of human origin, governed by the following acts:

(i) Legislative Decree No. 261 of 20 December 2007, revising Legislative Decree No. 191 of 19 August 2005, implementing Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components; Legislative Decree No. 207 of 9 November 2007, implementing Directive 2005/61/EC, which applies Directive 2002/98/EC as regards the traceability requirements for blood and blood components intended for transfusion and the notification of adverse reactions and serious incidents; Legislative Decree No. 208 of 9 November 2007, implementing Directive 2005/62/EC, which applies Directive 2002/98/EC as regards Community standards and specifications relating to a quality system for blood services;

(ii) Legislative Decree No. 191 of 6 November 2007, implementing Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

(iii) Decree of the Minister of Health of 19 November 2015, published in the Official Gazette No. 280 of 1 December 2015, implementing 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, pursuant to Article 1, paragraph 340, Law No. 228 of 24 December 2012, as well as implementing Commission Implementing Directive 2012/25/EU of 9 October 2012, establishing information procedures for the exchange between Member States of human organs intended for transplantation.

b) Measures establishing high standards of quality and safety for medicinal products and medical devices, governed by the following acts:

(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) Ministerial Decree No 279 of 18 May 2001, laying down rules for the national network for rare diseases and exemption from the cost of related healthcare services, pursuant to Article 5(1)(b) of Legislative Decree No 124 of 29 April 1998; Law No. 175 of 10 November 2021, containing provisions for the treatment of rare diseases and for the support of research and production of orphan drugs;

(iii) Legislative Decree No. 219 of 24 April 2006, implementing Directive 2001/83/EC (and subsequent amending directives) on the Community code relating to medicinal products for human use;

(iv) 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);

(v) 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);

(vi) 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);

(vii) 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); Article 3(1)(f-bis) of Legislative Decree No 219 of 24 April 2006; of the Minister of Health of 16 January 2015, published in Official Gazette No 56 of 9 March 2015, laying down provisions on advanced therapy medicinal products prepared on a non-repetitive basis; decree of the Minister of Health of 18 May 2010, published in the Official Gazette, No. 160, of 12 July 2010, implementing Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council as regards advanced therapy medicinal products;

(viii) 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 L158 of 27.5.2014, p. 1); Law No 3 of 11 January 2018, delegating powers to the Government in the field of clinical trials of medicinal products and laying down provisions for the reorganisation of the health professions and for the health management of the Ministry of Health; Decree of the Minister of Health of 19 April 2018, published in the Official Gazette No. 107 of 10 May 2018, establishing the National Coordination Centre of Regional Ethics Committees for Clinical Trials on Medicinal Products for Human Use and Medical Devices, pursuant to Article 2, paragraph 1, of Law No. 3 of 11 January 2018; Legislative Decree No. 52 of 14 May 2019, implementing the delegation for the reorganisation and reform of the legislation on clinical trials of medicinal products for human use, pursuant to Article 1, paragraphs 1 and 2, of Law No. 3 of 11 January 2018.

c) Patients' rights referred to in:

(i) Legislative Decree No. 38 of 4 March 2014, implementing Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, as well as Directive 2012/52/EU, containing measures to facilitate the recognition of medical prescriptions issued in another Member State; Ministerial Decree No. 50 of 16 April 2018. Regulations on cross-border healthcare subject to prior authorisation.

d) Processing, presentation and sale of tobacco products and related products, governed by Legislative Decree No. 6 of 12 January 2016, No. 6, transposing Directive 2014/40/EU 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.

▪ **Consumer rights and consumer protection governed by the following acts:**

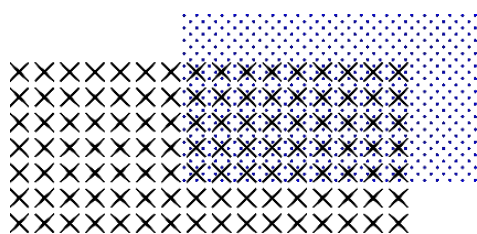
(i) Legislative Decree No. 206 of 6 September 2005, containing the Consumer Code, pursuant to Article 7 of Law No. 229 of 29 July 2003 No 229;

(ii) Legislative Decree No. 173 of 4 November 2021, implementing Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects of contracts for the supply of digital content and digital services;

(iii) Legislative Decree No. 170 of 4 November 2021, implementing Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects of contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC;

(iv) Legislative Decree No. 146 of 2 August 2007, implementing Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market and amending Directives 84/450/EEC, 97/7/EC, 98/27/EC, 2002/65/EC, and Regulation (EC) No 2006/2004;

(v) Legislative Decree No. 141 of 13 August 2010, implementing Directive 2008/48/EC on credit agreements for consumers, as well as amendments to Title VI of the Consolidated Banking Law (Legislative Decree No. 385 of 1993) concerning



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the regulation of entities operating in the financial sector, financial agents and credit intermediaries;

(vi) Legislative Decree No. 21 of 21 February 2014, implementing Directive 2011/83/EU on consumer rights, amending Directives 93/13/EEC and 1999/44/EC and repealing Directives 85/577/EEC and 97/7/EC;

(vii) Legislative Decree No. 37 of 15 March 2017, implementing Directive 2014/92/EU on the comparability of fees related to payment accounts, payment account switching and access to payment accounts with basic features.

▪ **Protection of privacy and personal data and security of networks and information systems:**

(i) Legislative Decree No. 196 of 30 June 2003, containing the code on the protection of personal data, laying down provisions for the adaptation of national legislation to Regulation (EU) No. 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 the free movement of such data and repealing Directive 95/46/EC;

(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); Legislative Decree No 101 of 10 August 2018 No. 101, containing provisions for the adaptation of national legislation to the provisions of 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).

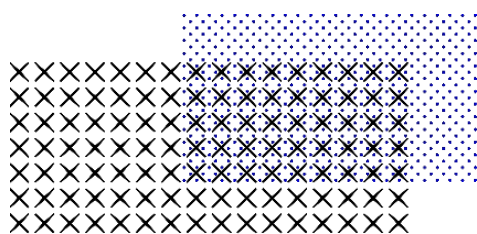
(iii) lawful activities falling within the scope of national acts implementing European Union acts relating to the following areas:

- public procurement;
- services, products and financial markets, and the prevention of money laundering and terrorist financing;
- product safety and compliance;
- transport safety;
- environmental protection;
- radiation protection and nuclear safety;
- food and feed safety and animal health and welfare;
- public health;
- consumer protection;
- protection of privacy and personal data and security of networks and information systems;

(iv) acts or omissions affecting the financial interests of the Union referred to in Article 325 of the Treaty on the Functioning of the European Union, as specified in the relevant secondary legislation of the European Union;

(v) acts or omissions affecting the internal market, as referred to in Article 26(2) of the Treaty on the Functioning of the European Union, including infringements of European Union competition and State aid rules, as well as infringements relating to the internal market connected with acts infringing company tax rules or arrangements whose purpose is to obtain a tax advantage that defeats the object or purpose of the applicable company tax legislation;

(vi) acts or conduct which defeat the object or purpose of the provisions of Union acts in the areas referred to in points (ii), (iii), (iiii) and (iv).



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