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THE EUROPEAN PARLIAMENT **THE COUNCIL**

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DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE PROTECTION OF PERSONS WHO REPORT BREACHES OF UNION LAW

DIRECTIVE (EU) 2019/…
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 23 October 2019

on the protection of persons who report breaches of Union law

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 16, Article 43(2), Article 50, Article 53(1), Articles 91, 100, and 114, Article 168(4), Article 169, Article 192(1) and Article 325(4) thereof and to the Treaty establishing the European Atomic Energy Community, and in particular Article 31 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the Court of Auditors[1],

Having regard to the opinion of the European Economic and Social Committee[2],

After consulting the Committee of the Regions,

Having regard to the opinion of 30 November 2018 of the Group of Experts referred to in Article 31 of the Treaty establishing the European Atomic Energy Community,

Acting in accordance with the ordinary legislative procedure[3],

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1 OJ C 405, 9.11.2018, p. 1.

2 OJ C 62, 15.2.2019, p. 155.

3 Position of the European Parliament of 16 April 2019 (not yet published in the Official Journal) and decision of the Council of 7 October 2019.

Whereas:

(1) Persons who work for a public or private organisation or are in contact with such an organisation in the context of their work-related activities are often the first to know about threats or harm to the public interest which arise in that context. By reporting breaches of Union law that are harmful to the public interest, such persons act as 'whistleblowers' and thereby play a key role in exposing and preventing such breaches and in safeguarding the welfare of society. However, potential whistleblowers are often discouraged from reporting their concerns or suspicions for fear of retaliation. In this context, the importance of providing balanced and effective whistleblower protection is increasingly acknowledged at both Union and international level.

(2) At Union level, reports and public disclosures by whistleblowers are one upstream component of enforcement of Union law and policies. They feed national and Union enforcement systems with information, leading to effective detection, investigation and prosecution of breaches of Union law, thus enhancing transparency and accountability.

(3) In certain policy areas, breaches of Union law, regardless of whether they are categorised under national law as administrative, criminal or other types of breaches, may cause serious harm to the public interest, in that they create significant risks for the welfare of society. Where weaknesses of enforcement have been identified in those areas, and whistleblowers are usually in a privileged position to disclose breaches, it is necessary to enhance enforcement by introducing effective, confidential and secure reporting channels and by ensuring that whistleblowers are protected effectively against retaliation.

(4) Whistleblower protection currently provided in the Union is fragmented across Member States and uneven across policy areas. The consequences of breaches of Union law with a cross-border dimension reported by whistleblowers illustrate how insufficient protection in one Member State negatively impacts the functioning of Union policies not only in that Member State, but also in other Member States and in the Union as a whole.

(5) Common minimum standards ensuring that whistleblowers are protected effectively should apply as regards acts and policy areas where there is a need to strengthen enforcement, under-reporting by whistleblowers is a key factor affecting enforcement, and breaches of Union law can cause serious harm to the public interest. Member States could decide to extend the application of national provisions to other areas with a view to ensuring that there is a comprehensive and coherent whistleblower protection framework at national level.

(6) Whistleblower protection is necessary to enhance the enforcement of Union law on public procurement. It is necessary, not only to prevent and detect procurement-related fraud and corruption in the context of the implementation of the Union budget, but also to tackle insufficient enforcement of rules on public procurement by national contracting authorities and contracting entities in relation to the execution of works, the supply of products or the provision of services. Breaches of such rules create distortions of competition, increase costs for doing business, undermine the interests of investors and shareholders and, in general, lower attractiveness for investment and create an uneven playing field for all businesses across the Union, thus affecting the proper functioning of the internal market.

(7) In the area of financial services, the added value of whistleblower protection has already been acknowledged by the Union legislator. In the aftermath of the financial crisis, which exposed serious shortcomings in the enforcement of the relevant rules, measures for the protection of whistleblowers, including internal and external reporting channels, as well as an explicit prohibition of retaliation, were introduced in a significant number of legislative acts in the area of financial services as indicated by the Commission in its communication of 8 December 2010 entitled 'Reinforcing sanctioning regimes in the financial services sector'. In particular, in the context of the prudential framework applicable to credit institutions and investment firms, Directive 2013/36/EU of the European Parliament and of the Council[1] provides for whistleblower protection which applies in the context of Regulation (EU) No 575/2013 of the European Parliament and of the Council[2].

[1] 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).

[2] 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).

(8) As regards the safety of products placed on the internal market, businesses involved in the manufacturing and distribution chain are the primary source of evidence, with the result that reporting by whistleblowers in such businesses has a high added value, since they are much closer to information about possible unfair and illicit manufacturing, import or distribution practices regarding unsafe products. Accordingly, there is a need to introduce whistleblower protection in relation to the safety requirements applicable to products regulated by the Union harmonisation legislation as set out in Annexes I and II to Regulation (EU) 2019/1020 of the European Parliament and of the Council[1], and in relation to the general product safety requirements as set out in Directive 2001/95/EC of the European Parliament and of the Council[2]. Whistleblower protection as provided for in this Directive would also be instrumental in avoiding diversion of firearms, their parts and components and ammunition, as well as of defence-related products, since it would encourage the reporting of breaches of Union law, such as document fraud, altered marking and fraudulent acquisition of firearms within the Union where breaches often imply a diversion from the legal to the illegal market. Whistleblower protection as provided for in this Directive would also help prevent the illicit manufacture of homemade explosives by contributing to the correct application of restrictions and controls regarding explosives precursors.

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[1] 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).

[2] 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).

(9) The importance of whistleblower protection in terms of preventing and deterring breaches of Union rules on transport safety, which can endanger human lives, has already been acknowledged in sectorial Union acts on aviation safety, namely in Regulation (EU) No 376/2014 of the European Parliament and of the Council[1], and maritime transport safety, namely in Directives 2013/54/EU[2] and 2009/16/EC[3] of the European Parliament and of the Council, which provide for tailored measures of protection for whistleblowers as well as specific reporting channels. Those acts also provide for the protection of workers who report their own honest mistakes against retaliation, so-called 'just culture'. It is necessary to complement the existing elements of whistleblower protection in those two sectors, as well as to provide protection in other transport modes, namely inland waterway, road and railway transport, to enhance the enforcement of safety standards as regards those transport modes.

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1 Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18).

2 Directive 2013/54/EU of the European Parliament and of the Council of 20 November 2013 concerning certain flag State responsibilities for compliance with and enforcement of the Maritime Labour Convention, 2006 (OJ L 329, 10.12.2013, p. 1).

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

(10) As regards the area of protection of the environment, evidence-gathering, preventing, detecting and addressing environmental crimes and unlawful conduct remain a challenge and actions in that regard need to be reinforced, as acknowledged by the Commission in its communication of 18 January 2018 entitled 'EU actions to improve environmental compliance and governance'. Given that before the entry into force of this Directive, the only existing whistleblower protection rules related to environmental protection are provided for in one sectorial act, namely Directive 2013/30/EU of the European Parliament and of the Council[1], the introduction of such protection is necessary to ensure effective enforcement of the Union environmental *acquis*, the breaches of which can cause harm to the public interest with possible spillover impacts across national borders. The introduction of such protection is also relevant in cases where unsafe products can cause environmental harm.

[1] Directive 2013/30/EU of the European Parliament and of the Council of 12 June 2013, on safety of offshore oil and gas operations and amending Directive 2004/35/EC (OJ L 178, 28.6.2013, p. 66).

(11) Enhancing whistleblower protection would also contribute to preventing and deterring breaches of European Atomic Energy Community rules on nuclear safety, radiation protection and responsible and safe management of spent fuel and radioactive waste. It would also strengthen the enforcement of the relevant provisions of Council Directive 2009/71/Euratom[1], concerning promotion and enhancement of an effective nuclear safety culture and, in particular, point (a) of Article 8b(2) of that Directive, which requires, inter alia, that the competent regulatory authority establishes management systems which give due priority to nuclear safety and promote, at all levels of staff and management, the ability to question the effective delivery of relevant safety principles and practices and to report in a timely manner on safety issues.

[1] 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).

(12) The introduction of a whistleblower protection framework would also contribute to strengthening the enforcement of existing provisions, and to preventing breaches of Union rules, in the area of the food chain and, in particular, on food and feed safety, as well as on animal health, protection and welfare. The different Union rules laid down in those areas are closely interlinked. Regulation (EC) No 178/2002 of the European Parliament and of the Council[1] sets out the general principles and requirements which underpin all Union and national measures relating to food and feed, with a particular focus on food safety, in order to ensure a high level of protection of human health and consumers' interests in relation to food, as well as the effective functioning of the internal market. That Regulation provides, inter alia, that food and feed business operators are prevented from discouraging their employees and others from cooperating with competent authorities where such cooperation could prevent, reduce or eliminate a risk arising from food.

[1] 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).

The Union legislator has taken a similar approach in the area of animal health through Regulation (EU) 2016/429 of the European Parliament and of the Council[1] establishing the rules for the prevention and control of animal diseases which are transmissible to animals or to humans and in the area of the protection and well-being of animals kept for farming purposes, of animals used for scientific purposes, of animals during transport and of animals at the time of killing, through Council Directive 98/58/EC[2] and Directive 2010/63/EU of the European Parliament and of the Council[3], as well as Council Regulations (EC) No 1/2005[4] and (EC) No 1099/2009[5], respectively.

(13) The reporting of breaches by whistleblowers can be key to detecting and preventing, reducing or eliminating risks to public health and to consumer protection resulting from breaches of Union rules, which might otherwise remain hidden. In particular, consumer protection is also strongly linked to cases where unsafe products can cause considerable harm to consumers.

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1 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).

2 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).

3 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).

4 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).

5 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).

(14) Respect for privacy and protection of personal data, which are enshrined as fundamental rights in Articles 7 and 8 of the Charter of Fundamental Rights of the European Union (the 'Charter'), are other areas in which whistleblowers can help to disclose breaches, which can harm the public interest. Whistleblowers can also help disclose breaches of Directive (EU) 2016/1148 of the European Parliament and of the Council[1] on the security of network and information systems, which introduces a requirement to provide notification of incidents, including those that do not compromise personal data, and security requirements for entities providing essential services across many sectors, for example energy, health, transport and banking, for providers of key digital services, for example cloud computing services, and for suppliers of basic utilities, such as water, electricity and gas. Whistleblowers' reporting in this area is particularly valuable for the prevention of security incidents that would affect key economic and social activities and widely used digital services, as well as for the prevention of any infringement of Union data protection rules. Such reporting helps ensure the continuity of services that are essential for the functioning of the internal market and the wellbeing of society.

[1] 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).

(15) Furthermore, the protection of the financial interests of the Union, which is related to the fight against fraud, corruption and any other illegal activity affecting Union expenditure, the collection of Union revenues and funds or Union assets, is a core area in which enforcement of Union law needs to be strengthened. The strengthening of the protection of the financial interests of the Union is relevant also for the implementation of the Union budget as regards expenditure that is incurred on the basis of the Treaty establishing the European Atomic Energy Community (Euratom Treaty). Lack of effective enforcement in the area of protection of the financial interests of the Union, including as regards prevention of fraud and corruption at national level, leads to a decrease of Union revenues and a misuse of Union funds, which can distort public investments, hinder growth and undermine citizens' trust in Union action. Article 325 of the Treaty on the Functioning of the European Union (TFEU) requires the Union and the Member States to counter fraud and any other illegal activities affecting the financial interests of the Union. Relevant Union measures in this respect include, in particular, Council Regulation (EC, Euratom) No 2988/95[1] and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[2].

[1] Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

[2] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

Regulation (EC, Euratom) No 2988/95 is complemented, for the most serious types of fraud-related conduct, by Directive (EU) 2017/1371 of the European Parliament and of the Council[1] and by the Convention drawn up on the basis of Article K.3 of the Treaty on European Union, on the protection of the European Communities' financial interests of 26 July 1995[2], including the Protocols thereto of 27 September 1996[3], of 29 November 1996[4] and of 19 June 1997[5]. That Convention and those Protocols remain in force for the Member States not bound by Directive (EU) 2017/1371.

(16) Common minimum standards for the protection of whistleblowers should also be laid down for breaches relating to the internal market as referred to in Article 26(2) TFEU. In addition, in accordance with the case law of the Court of Justice of the European Union (the 'Court'), Union measures aimed at establishing or ensuring the functioning of the internal market are intended to contribute to the elimination of existing or emerging obstacles to the free movement of goods or to the freedom to provide services, and to contribute to the removal of distortions of competition.

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1 Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29).

2 OJ C 316, 27.11.1995, p. 49.

3 OJ C 313, 23.10.1996, p. 2.

4 OJ C 151, 20.5.1997, p. 2.

5 OJ C 221, 19.7.1997, p. 2.

(17) Specifically, the protection of whistleblowers to enhance the enforcement of Union competition law, including concerning State aid, would serve to safeguard the efficient functioning of markets in the Union, allow a level playing field for business and deliver benefits to consumers. As regards competition rules applying to undertakings, the importance of insider reporting in detecting competition law infringements has already been recognised in the leniency policy pursued by the Commission under Article 4a of Commission Regulation (EC) No 773/2004[1] as well as with the recent introduction of an anonymous whistleblower tool by the Commission. Breaches relating to competition law and State aid rules concern Articles 101, 102, 106, 107 and 108 TFEU and rules of secondary law adopted for their application.

[1] Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the EC Treaty (OJ L 123, 27.4.2004, p. 18).

(18) Breaches of corporate tax law and arrangements of which the purpose is to obtain a tax advantage and to evade legal obligations, thereby defeating the object or purpose of the applicable corporate tax law, negatively affect the proper functioning of the internal market. Such breaches and arrangements can give rise to unfair tax competition and extensive tax evasion, distorting the level playing field for businesses and resulting in a loss of tax revenues for Member States and for the Union budget as a whole. This Directive should provide for protection against retaliation for persons who report evasive and/or abusive arrangements that could otherwise go undetected, with a view to strengthening the ability of competent authorities to safeguard the proper functioning of the internal market and remove distortions and barriers to trade that affect the competitiveness of businesses in the internal market, and that are directly linked to the free movement rules and are also relevant for the application of the State aid rules. Whistleblower protection as provided for in this Directive would add to recent Commission initiatives aimed at improving transparency and the exchange of information in the field of taxation, and creating a fairer corporate tax environment within the Union with a view to increasing Member States' effectiveness in identifying evasive and/or abusive arrangements, and would help deter such arrangements. However, this Directive does not harmonise provisions relating to taxes, whether substantive or procedural, and does not seek to strengthen the enforcement of national corporate tax rules, without prejudice to the possibility of Member States to use reported information for that purpose.

(19) Point (a) of Article 2(1) defines the material scope of this Directive by means of a reference to a list of Union acts set out in the Annex. This implies that where those Union acts, in turn, define their material scope by reference to Union acts listed in their annexes, the latter acts also form part of the material scope of this Directive. In addition, the reference to the acts in the Annex should be understood as including all national and Union implementing or delegated measures adopted pursuant to those acts. Moreover, the reference to the Union acts in the Annex is to be understood as a dynamic reference, in accordance with the standard referencing system for legal acts of the Union. Thus, if a Union act in the Annex has been or is amended, the reference relates to the act as amended; if a Union act in the Annex has been or is replaced, the reference relates to the new act.

(20) Certain Union acts, in particular in the area of financial services, such as Regulation (EU) No 596/2014 of the European Parliament and of the Council[1], and Commission Implementing Directive (EU) 2015/2392[2], adopted on the basis of that Regulation, already contain detailed rules on whistleblower protection. Any specific rules in that regard provided for in such existing Union legislation, including the Union acts listed in Part II of the Annex to this Directive, which are tailored to the relevant sectors, should be maintained. This is of particular importance for ascertaining which legal entities in the area of financial services, the prevention of money laundering and terrorist financing are currently obliged to establish internal reporting channels. At the same time, in order to ensure consistency and legal certainty across Member States, this Directive should be applicable in respect of all matters not regulated under the sector-specific acts, and thereby should complement such acts, so that they are fully aligned with minimum standards. In particular, this Directive should provide further detail as to the design of the internal and external reporting channels, the obligations of competent authorities, and the specific forms of protection to be provided at national level against retaliation.

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[1] Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation) and repealing Directive 2003/6/EC of the European Parliament and of the Council and Commission Directives 2003/124/EC, 2003/125/EC and 2004/72/EC (OJ L 173, 12.6.2014, p. 1).

[2] Commission Implementing Directive (EU) 2015/2392 of 17 December 2015 on Regulation (EU) No 596/2014 of the European Parliament and of the Council as regards reporting to competent authorities of actual or potential infringements of that Regulation (OJ L 332, 18.12.2015, p. 126).

In that regard, Article 28(4) of Regulation (EU) No 1286/2014 of the European Parliament and of the Council[1] provides for Member States to be able to provide for an internal reporting channel in the area covered by that Regulation. For reasons of consistency with the minimum standards laid down by this Directive, the obligation to establish internal reporting channels provided for in this Directive should also apply in respect of Regulation (EU) No 1286/2014.

(21) This Directive should be without prejudice to the protection granted to workers when reporting breaches of Union employment law. In particular, in the area of occupational safety and health, Article 11 of Council Directive 89/391/EEC[2] already requires Member States to ensure that workers or workers' representatives are not placed at a disadvantage because of requests or proposals they make to employers to take appropriate measures to mitigate hazards for workers and/or to remove sources of danger. Workers and their representatives are entitled, under that Directive, to raise issues with the competent authority if they consider that the measures taken, and the means employed, by the employer are inadequate for the purposes of ensuring safety and health.

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1 Regulation (EU) No 1286/2014 of the European Parliament and of the Council of 26 November 2014 on key information documents for packaged retail and insurance-based investment products (PRIIPs) (OJ L 352, 9.12.2014, p. 1).

2 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

(22) Member States could decide to provide that reports concerning interpersonal grievances exclusively affecting the reporting person, namely grievances about interpersonal conflicts between the reporting person and another worker, can be channelled to other procedures.

(23) This Directive should be without prejudice to the protection granted by the procedures for reporting possible illegal activities, including fraud or corruption, that are detrimental to the interests of the Union, or for reporting conduct relating to the discharge of professional duties, which could constitute a serious failure to comply with the obligations of officials and other servants of the European Union established under Articles 22a, 22b and 22c of the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68[1]. This Directive should apply where officials and other servants of the Union report breaches that occur in a work-related context outside their employment relationship with the Union institutions, bodies, offices or agencies.

[1] OJ L 56, 4.3.1968, p. 1.

(24) National security remains the sole responsibility of each Member State. This Directive should not apply to reports of breaches related to procurement involving defence or security aspects where those are covered by Article 346 TFEU, in accordance with the case law of the Court. If Member States decide to extend the protection provided under this Directive to further areas or acts, which are not within its material scope, it should be possible for them to adopt specific provisions to protect essential interests of national security in that regard.

(25) This Directive should also be without prejudice to the protection of classified information which Union law or the laws, regulations or administrative provisions in force in the Member State concerned require, for security reasons, to be protected from unauthorised access. Moreover, this Directive should not affect the obligations arising from Council Decision 2013/488/EU[1] or Commission Decision (EU, Euratom) 2015/444[2].

(26) This Directive should not affect the protection of confidentiality of communications between lawyers and their clients ('legal professional privilege') as provided for under national and, where applicable, Union law, in accordance with the case law of the Court. Moreover, this Directive should not affect the obligation of maintaining the confidential nature of communications of health care providers, including therapists, with their patients and of patient records ('medical privacy') as provided for under national and Union law.

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1 Council Decision 2013/488/EU of 23 September 2013 on the security rules for protecting EU classified information (OJ L 274, 15.10.2013, p. 1).

2 Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

(27) Members of professions other than lawyers and health care providers should be able to qualify for protection under this Directive when they report information protected by the applicable professional rules, provided that reporting that information is necessary for the purposes of revealing a breach falling within the scope of this Directive.

(28) While this Directive should provide, under certain conditions, for a limited exemption from liability, including criminal liability, in the event of a breach of confidentiality, it should not affect national rules on criminal procedure, particularly those aiming at safeguarding the integrity of the investigations and proceedings or the rights of defence of persons concerned. This should be without prejudice to the introduction of measures of protection into other types of national procedural law, in particular, the reversal of the burden of proof in national administrative, civil or labour proceedings.

(29) This Directive should not affect national rules on the exercise of the rights of employees' representatives to information, consultation, and participation in collective bargaining and their defence of workers' employment rights. This should be without prejudice to the level of protection granted under this Directive.

(30) This Directive should not apply to cases in which persons who, having given their informed consent, have been identified as informants or registered as such in databases managed by authorities appointed at national level, such as customs authorities, and report breaches to enforcement authorities, in return for reward or compensation. Such reports are made pursuant to specific procedures that aim to guarantee the anonymity of such persons in order to protect their physical integrity, and that are distinct from the reporting channels provided for under this Directive.

(31) Persons who report information about threats or harm to the public interest obtained in the context of their work-related activities make use of their right to freedom of expression. The right to freedom of expression and information, enshrined in Article 11 of the Charter and in Article 10 of the Convention for the Protection of Human Rights and Fundamental Freedoms, encompasses the right to receive and impart information as well as the freedom and pluralism of the media. Accordingly, this Directive draws upon the case law of the European Court of Human Rights (ECHR) on the right to freedom of expression, and the principles developed on this basis by the Council of Europe in its Recommendation on the Protection of Whistleblowers adopted by its Committee of Ministers on 30 April 2014.

(32) To enjoy protection under this Directive, reporting persons should have reasonable grounds to believe, in light of the circumstances and the information available to them at the time of reporting, that the matters reported by them are true. That requirement is an essential safeguard against malicious and frivolous or abusive reports as it ensures that those who, at the time of the reporting, deliberately and knowingly reported wrong or misleading information do not enjoy protection. At the same time, the requirement ensures that protection is not lost where the reporting person reported inaccurate information on breaches by honest mistake. Similarly, reporting persons should be entitled to protection under this Directive if they have reasonable grounds to believe that the information reported falls within its scope. The motives of the reporting persons in reporting should be irrelevant in deciding whether they should receive protection.

(33) Reporting persons normally feel more at ease reporting internally, unless they have reasons to report externally. Empirical studies show that the majority of whistleblowers tend to report internally, within the organisation in which they work. Internal reporting is also the best way to get information to the persons who can contribute to the early and effective resolution of risks to the public interest. At the same time, the reporting person should be able to choose the most appropriate reporting channel depending on the individual circumstances of the case. Moreover, it is necessary to protect public disclosures, taking into account democratic principles such as transparency and accountability, and fundamental rights such as freedom of expression and the freedom and pluralism of the media, whilst balancing the interest of employers to manage their organisations and to protect their interests, on the one hand, with the interest of the public to be protected from harm, on the other, in line with the criteria developed in the case law of the ECHR.

(34) Without prejudice to existing obligations to provide for anonymous reporting by virtue of Union law, it should be possible for Member States to decide whether legal entities in the private and public sector and competent authorities are required to accept and follow up on anonymous reports of breaches which fall within the scope of this Directive. However, persons who anonymously reported or who made anonymous public disclosures falling within the scope of this Directive and meet its conditions should enjoy protection under this Directive if they are subsequently identified and suffer retaliation.

(35) This Directive should provide for protection to be granted in cases where persons report, pursuant to Union legislation, to institutions, bodies, offices or agencies of the Union, for example in the context of fraud concerning the Union budget.

(36) Persons need specific legal protection where they acquire the information they report through their work-related activities and therefore run the risk of work-related retaliation, for instance, for breaching the duty of confidentiality or loyalty. The underlying reason for providing such persons with protection is their position of economic vulnerability vis-à-vis the person on whom *de facto* they depend for work. Where there is no such work-related power imbalance, for instance in the case of ordinary complainants or citizen bystanders, there is no need for protection against retaliation.

(37) Effective enforcement of Union law requires that protection should be granted to the broadest possible range of categories of persons, who, irrespective of whether they are Union citizens or third-country nationals, by virtue of their work-related activities, irrespective of the nature of those activities and of whether they are paid or not, have privileged access to information on breaches that it would be in the public interest to report and who may suffer retaliation if they report them. Member States should ensure that the need for protection is determined by reference to all the relevant circumstances and not merely by reference to the nature of the relationship, so as to cover the whole range of persons connected in a broad sense to the organisation where the breach has occurred.

(38) Protection should, firstly, apply to persons having the status of 'workers', within the meaning of Article 45(1) TFEU, as interpreted by the Court, namely persons who, for a certain period of time, perform services for and under the direction of another person, in return for which they receive remuneration. Protection should, thus, also be granted to workers in non-standard employment relationships, including part-time workers and fixed-term contract workers, as well as persons with a contract of employment or employment relationship with a temporary agency, precarious types of relationships where standard forms of protection against unfair treatment are often difficult to apply. The concept of 'worker' also includes civil servants, public service employees, as well as any other persons working in the public sector.

(39) Protection should also extend to categories of natural persons, who, whilst not being 'workers' within the meaning of Article 45(1) TFEU, can play a key role in exposing breaches of Union law and may find themselves in a position of economic vulnerability in the context of their work-related activities. For instance, as regards product safety, suppliers are much closer to the source of information about possible unfair and illicit manufacturing, import or distribution practices concerning unsafe products; and as regards the implementation of Union funds, consultants providing their services are in a privileged position to draw attention to breaches they witness. Such categories of persons, which include self-employed persons providing services, freelance workers, contractors, subcontractors and suppliers, are typically subject to retaliation, which can take the form, for instance, of early termination or cancellation of a contract for services, a licence or permit, loss of business, loss of income, coercion, intimidation or harassment, blacklisting or business boycotting or damage to their reputation. Shareholders and persons in managerial bodies can also suffer retaliation, for instance in financial terms or in the form of intimidation or harassment, blacklisting or damage to their reputation. Protection should also be granted to persons whose work-based relationship has ended, and to candidates for employment or persons seeking to provide services to an organisation, who acquire information on breaches during the recruitment process or another pre-contractual negotiation stage, and who could suffer retaliation, for instance in the form of negative employment references, blacklisting or business boycotting.

(40) Effective whistleblower protection implies protecting also categories of persons who, whilst not relying on their work-related activities economically, can nevertheless suffer retaliation for reporting breaches. Retaliation against volunteers and paid or unpaid trainees could take the form of no longer making use of their services, or of giving them a negative employment reference or otherwise damaging their reputation or career prospects.

(41) Protection should be provided against retaliatory measures taken not only directly vis-à-vis reporting persons themselves, but also those that can be taken indirectly, including vis-à-vis facilitators, colleagues or relatives of the reporting person who are also in a work-related connection with the reporting person's employer or customer or recipient of services. Without prejudice to the protection that trade union representatives or employees' representatives enjoy in their capacity as such representatives under other Union and national rules, they should enjoy the protection provided for under this Directive both where they report in their capacity as workers and where they have provided advice and support to the reporting person. Indirect retaliation also includes actions taken against the legal entity that the reporting person owns, works for or is otherwise connected with in a work-related context, such as denial of provision of services, blacklisting or business boycotting.

(42) Effective detection and prevention of serious harm to the public interest requires that the notion of breach also includes abusive practices, as defined by the case law of the Court, namely acts or omissions which do not appear to be unlawful in formal terms but defeat the object or the purpose of the law.

(43) Effective prevention of breaches of Union law requires that protection is granted to persons who provide information necessary to reveal breaches which have already taken place, breaches which have not yet materialised, but are very likely to take place, acts or omissions which the reporting person has reasonable grounds to consider as breaches, as well as attempts to conceal breaches. For the same reasons, protection is justified also for persons who do not provide positive evidence but raise reasonable concerns or suspicions. At the same time, protection should not apply to persons who report information which is already fully available in the public domain or unsubstantiated rumours and hearsay.

(44) There should be a close link between reporting and the adverse treatment suffered, directly or indirectly, by the reporting person, for that adverse treatment to be considered to be retaliation and consequently for the reporting person to be able to enjoy legal protection in that respect. Effective protection of reporting persons as a means of enhancing the enforcement of Union law requires a broad definition of retaliation, encompassing any act or omission occurring in a work-related context and which causes them detriment. This Directive should not, however, prevent employers from taking employment-related decisions which are not prompted by the reporting or public disclosure.

(45) Protection against retaliation as a means of safeguarding freedom of expression and the freedom and pluralism of the media should be provided both to persons who report information about acts or omissions within an organisation ('internal reporting') or to an outside authority ('external reporting') and to persons who make such information available in the public domain, for instance, directly to the public through online platforms or social media, or to the media, elected officials, civil society organisations, trade unions, or professional and business organisations.

(46) Whistleblowers are, in particular, important sources for investigative journalists. Providing effective protection to whistleblowers from retaliation increases legal certainty for potential whistleblowers and thereby encourages whistleblowing also through the media. In this respect, protection of whistleblowers as journalistic sources is crucial for safeguarding the 'watchdog' role of investigative journalism in democratic societies.

(47) For the effective detection and prevention of breaches of Union law, it is vital that the relevant information reaches swiftly those closest to the source of the problem, most able to investigate and with powers to remedy it, where possible. As a principle, therefore, reporting persons should be encouraged to first use internal reporting channels and report to their employer, if such channels are available to them and can reasonably be expected to work. That is the case, in particular, where reporting persons believe that the breach can be effectively addressed within the relevant organisation, and that there is no risk of retaliation. As a consequence, legal entities in the private and public sector should establish appropriate internal procedures for receiving and following up on reports. Such encouragement also concerns cases where such channels were established without it being required by Union or national law. This principle should help foster a culture of good communication and corporate social responsibility in organisations, whereby reporting persons are considered to significantly contribute to self-correction and excellence within the organisation.

(48) For legal entities in the private sector, the obligation to establish internal reporting channels should be commensurate with their size and the level of risk their activities pose to the public interest. All enterprises having 50 or more workers should be subject to the obligation to establish internal reporting channels, irrespective of the nature of their activities, based on their obligation to collect VAT. Following an appropriate risk assessment, Member States could also require other enterprises to establish internal reporting channels in specific cases, for instance due to the significant risks that may result from their activities.

(49) This Directive should be without prejudice to Member States being able to encourage legal entities in the private sector with fewer than 50 workers to establish internal channels for reporting and follow-up, including by laying down less prescriptive requirements for those channels than those laid down under this Directive, provided that those requirements guarantee confidentiality and diligent follow-up.

(50) The exemption of small and micro enterprises from the obligation to establish internal reporting channels should not apply to private enterprises which are obliged to establish internal reporting channels by virtue of Union acts referred to in Parts I.B and II of the Annex.

(51) It should be clear that, in the case of legal entities in the private sector that do not provide for internal reporting channels, reporting persons should be able to report externally to the competent authorities and such persons should enjoy the protection against retaliation provided by this Directive.

(52) In order to ensure, in particular, that the public procurement rules in the public sector are respected, the obligation to put in place internal reporting channels should apply to all contracting authorities and contracting entities, at local, regional and national level, whilst being commensurate with their size.

(53) Provided the confidentiality of the identity of the reporting person is ensured, it is up to each individual legal entity in the private and public sector to define the kind of reporting channels to establish. More specifically, the reporting channels should enable persons to report in writing and submit reports by post, by physical complaint box(es), or through an online platform, whether it be on an intranet or internet platform, or to report orally, by telephone hotline or other voice messaging system, or both. Upon request by the reporting person, such channels should also enable reporting by means of physical meetings, within a reasonable timeframe.

(54) Third parties could also be authorised to receive reports of breaches on behalf of legal entities in the private and public sector, provided they offer appropriate guarantees of respect for independence, confidentiality, data protection and secrecy. Such third parties could be external reporting platform providers, external counsel, auditors, trade union representatives or employees' representatives.

(55) Internal reporting procedures should enable legal entities in the private sector to receive and investigate in full confidentiality reports by the workers of the entity and of its subsidiaries or affiliates ('the group'), but also, to any extent possible, by any of the group's agents and suppliers and by any persons who acquire information through their work-related activities with the entity and the group.

(56) The choice of the most appropriate persons or departments within a legal entity in the private sector to be designated as competent to receive and follow up on reports depends on the structure of the entity, but, in any case, their function should be such as to ensure independence and absence of conflict of interest. In smaller entities, this function could be a dual function held by a company officer well placed to report directly to the organisational head, such as a chief compliance or human resources officer, an integrity officer, a legal or privacy officer, a chief financial officer, a chief audit executive or a member of the board.

(57) In the context of internal reporting, informing, as far as legally possible and in the most comprehensive way possible, the reporting person about the follow-up to the report is crucial for building trust in the effectiveness of the overall system of whistleblower protection and reduces the likelihood of further unnecessary reports or public disclosures. The reporting person should be informed within a reasonable timeframe about the action envisaged or taken as follow-up to the report and the grounds for the choice of that follow-up. Follow-up could include, for instance, referral to other channels or procedures in the case of reports exclusively affecting individual rights of the reporting person, closure of the procedure based on lack of sufficient evidence or other grounds, launch of an internal enquiry and, possibly, its findings and any measures taken to address the issue raised, referral to a competent authority for further investigation, insofar as such information would not prejudice the internal enquiry or the investigation or affect the rights of the person concerned. In all cases, the reporting person should be informed of the investigation's progress and outcome. It should be possible to ask the reporting person to provide further information, during the course of the investigation, albeit without there being an obligation to provide such information.

(58) A reasonable timeframe for informing a reporting person should not exceed three months. Where the appropriate follow-up is still being determined, the reporting person should be informed about this and about any further feedback to expect.

(59) Persons who are considering reporting breaches of Union law should be able to make an informed decision on whether, how and when to report. Legal entities in the private and public sector that have internal reporting procedures in place should be required to provide information on those procedures as well as on external reporting procedures to relevant competent authorities. It is essential that such information be clear and easily accessible, including, to any extent possible, also to persons other than workers, who come in contact with the entity through their work-related activities, such as service-providers, distributors, suppliers and business partners. For instance, such information could be posted at a visible location accessible to all such persons and on the website of the entity, and could also be included in courses and training seminars on ethics and integrity.

(60) Effective detection and prevention of breaches of Union law require ensuring that potential whistleblowers can easily and in full confidentiality bring the information they possess to the attention of the relevant competent authorities that are able to investigate and to remedy the problem, where possible.

(61) It may be the case that internal channels do not exist or that they were used but did not function properly, for instance because the report was not dealt with diligently or within a reasonable timeframe, or no appropriate action was taken to address the breach despite the results of the related internal enquiry confirming the existence of a breach.

(62) In other cases, the use of internal channels cannot reasonably be expected to function properly. This is most notably the case where reporting persons have valid reasons to believe that they would suffer retaliation in connection with the reporting, including as a result of a breach of confidentiality, or that competent authorities would be better placed to take effective action to address the breach. Competent authorities would be better placed, for example, where the ultimate responsibility holder within the work-related context is involved in the breach, or there is a risk that the breach or related evidence could be concealed or destroyed; or, more generally, the effectiveness of investigative actions by competent authorities might otherwise be jeopardised, such as in the case of reported cartel arrangements and other breaches of competition rules; or the breach requires urgent action, for instance to safeguard the health and safety of persons or to protect the environment. In all cases, persons reporting externally to the competent authorities and, where relevant, to institutions, bodies, offices or agencies of the Union should be protected. This Directive should also grant protection where Union or national law requires the reporting persons to report to the competent national authorities, for instance as part of their job duties and responsibilities or because the breach is a criminal offence.

(63) Lack of confidence in the effectiveness of reporting is one of the main factors discouraging potential whistleblowers. Accordingly, there is a need to impose a clear obligation on competent authorities to establish appropriate external reporting channels, to diligently follow up on the reports received, and, within a reasonable timeframe, give feedback to reporting persons.

(64) It should be for the Member States to designate the authorities competent to receive information on breaches falling within the scope of this Directive and give appropriate follow-up to the reports. Such competent authorities could be judicial authorities, regulatory or supervisory bodies competent in the specific areas concerned, or authorities of a more general competence at a central level within a Member State, law enforcement agencies, anticorruption bodies or ombudsmen.

(65) As recipients of reports, the authorities designated as competent should have the necessary capacities and powers to ensure appropriate follow-up, including assessing the accuracy of the allegations made in the report and addressing the breaches reported by launching an internal enquiry, investigation, prosecution or action for recovery of funds, or other appropriate remedial action, in accordance with their mandate. Alternatively, those authorities should have the necessary powers to refer the report to another authority that should investigate the breach reported, while ensuring that there is appropriate follow-up by such authority. In particular, where Member States wish to establish external reporting channels at a central level, for instance in the area of State aid, Member States should put in place adequate safeguards in order to ensure that the requirements of independence and autonomy laid down in this Directive are respected. The establishment of such external reporting channels should not affect the powers of the Member States or of the Commission concerning supervision in the field of State aid, nor should this Directive affect the exclusive power of the Commission as regards the declaration of compatibility of State aid measures in particular pursuant to Article 107(3) TFEU. With regard to breaches of Articles 101 and 102 TFEU, Member States should designate as competent authorities those referred to in Article 35 of Council Regulation (EC) No 1/2003[1] without prejudice to the powers of the Commission in this area.

[1] Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (OJ L 1, 4.1.2003, p. 1).

(66) Competent authorities should also give feedback to the reporting persons about the action envisaged or taken as follow-up, for instance, referral to another authority, closure of the procedure based on lack of sufficient evidence or other grounds, or launch of an investigation, and possibly its findings and any measures taken to address the issue raised, as well as about the grounds for the choice of that follow-up. Communications on the final outcome of the investigations should not affect the applicable Union rules, which include possible restrictions on the publication of decisions in the area of financial regulation. This should apply *mutatis mutandis* in the field of corporate taxation, if similar restrictions are provided for by the applicable national law.

(67) Follow-up and feedback should take place within a reasonable timeframe, given the need to promptly address the problem that is the subject of the report, as well as the need to avoid unnecessary public disclosures. Such timeframe should not exceed three months, but could be extended to six months where necessary due to the specific circumstances of the case, in particular the nature and complexity of the subject of the report, which may require a lengthy investigation.

(68) Union law in specific areas, such as market abuse, namely Regulation (EU) No 596/2014 and Implementing Directive (EU) 2015/2392, civil aviation, namely Regulation (EU) No 376/2014, or safety of offshore oil and gas operations, namely Directive 2013/30/EU, already provides for the establishment of internal and external reporting channels. The obligations to establish such channels laid down in this Directive should build as far as possible on the existing channels provided by specific Union acts.

(69) The Commission, as well as some bodies, offices and agencies of the Union, such as the European Anti-Fraud Office (OLAF), the European Maritime Safety Agency (EMSA), the European Aviation Safety Agency (EASA), the European Security and Markets Authority (ESMA) and the European Medicines Agency (EMA), have in place external reporting channels and procedures for receiving reports of breaches falling within the scope of this Directive, which mainly provide for confidentiality of the identity of the reporting persons. This Directive should not affect such external reporting channels and procedures, where they exist, but should ensure that persons reporting to institutions, bodies, offices or agencies of the Union benefit from common minimum standards of protection throughout the Union.

(70) To ensure the effectiveness of the procedures for following up on reports and addressing breaches of the Union rules concerned, Member States should be able to take measures to alleviate burdens for competent authorities resulting from reports of minor breaches of provisions falling within the scope of this Directive, repetitive reports or reports of breaches of ancillary provisions, for instance provisions on documentation or notification obligations. Such measures could consist in allowing competent authorities, after due assessment of the matter, to decide that a reported breach is clearly minor and does not require further follow-up pursuant to this Directive, other than closure of the procedure. It should also be possible for Member States to allow competent authorities to close the procedure regarding repetitive reports which do not contain any meaningful new information adding to a past report in respect of which the relevant procedures were concluded, unless new legal or factual circumstances justify a different form of follow-up. Furthermore, Member States should be able to allow competent authorities to prioritise the treatment of reports of serious breaches or breaches of essential provisions falling within the scope of this Directive in the event of high inflows of reports.

(71) Where provided for under Union or national law, the competent authorities should refer cases or relevant information on breaches to institutions, bodies, offices or agencies of the Union, including, for the purposes of this Directive, OLAF and the European Public Prosecutor Office (EPPO), without prejudice to the possibility for the reporting person to refer directly to such bodies, offices or agencies of the Union.

(72) In many policy areas falling within the material scope of this Directive, there are cooperation mechanisms through which national competent authorities exchange information and carry out follow-up activities in relation to breaches of Union rules with a cross-border dimension. Examples range from the Administrative Assistance and Cooperation System established by Commission Implementing Decision (EU) 2015/1918[1], in cases of cross-border breaches of the Union agri-food chain legislation, and the Food Fraud Network under Regulation (EC) No 882/2004 of the European Parliament and of the Council[2], the rapid alert system for dangerous non-food products established by Regulation (EC) No 178/2002 of the European Parliament and of the Council[3], the Consumer Protection Cooperation Network under Regulation (EC) No 2006/2004 of the European Parliament and of the Council[4], to the Environmental Compliance and Governance Forum set up by the Commission Decision of 18 January 2018[5], the European Competition Network established pursuant to Regulation (EC) No 1/2003, and the administrative cooperation in the field of taxation under Council Directive 2011/16/EU[6].

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1 Commission Implementing Decision (EU) 2015/1918 of 22 October 2015 establishing the Administrative Assistance and Cooperation system ('AAC system') pursuant to Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 280, 24.10.2015, p. 31).

2 Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

3 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).

4 Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (the Regulation on consumer protection cooperation) (OJ L 364, 9.12.2004, p. 1).

5 Commission Decision of 18 January 2018 setting up a group of experts on environmental compliance and governance (OJ C 19, 19.1.2018, p. 3).

6 Council Directive 2011/16/EU of 15 February 2011 on administrative cooperation in the field of taxation and repealing Directive 77/799/EEC (OJ L 64, 11.3.2011, p. 1).

Member States' competent authorities should make full use of such existing cooperation mechanisms where relevant as part of their obligation to follow up on reports regarding breaches falling within the scope of this Directive. In addition, Member States' authorities could also cooperate beyond the existing cooperation mechanisms in cases of breaches with a cross-border dimension in areas where such cooperation mechanisms do not exist.

(73) In order to enable effective communication with staff members who are responsible for handling reports, it is necessary that the competent authorities have in place channels that are user-friendly, secure, ensure confidentiality for receiving and handling information provided by the reporting person on breaches, and that enable the durable storage of information to allow for further investigations. This could require that such channels are separated from the general channels through which the competent authorities communicate with the public, such as normal public complaints systems or channels through which the competent authority communicates internally and with third parties in its ordinary course of business.

(74) Staff members of the competent authorities who are responsible for handling reports should be professionally trained, including on applicable data protection rules, in order to handle reports and to ensure communication with the reporting person, as well as to follow up on the report in a suitable manner.

(75) Persons intending to report should be able to make an informed decision on whether, how and when to report. Competent authorities should therefore provide clear and easily accessible information about the available reporting channels with competent authorities, about the applicable procedures and about the staff members responsible for handling reports within those authorities. All information regarding reports should be transparent, easily understandable and reliable in order to promote and not deter reporting.

(76) Member States should ensure that competent authorities have in place adequate protection procedures for the processing of reports and for the protection of the personal data of the persons referred to in the report. Such procedures should ensure that the identity of every reporting person, person concerned, and third persons referred to in the report, for example witnesses or colleagues, is protected at all stages of the procedure.

(77) It is necessary that staff members of the competent authority who are responsible for handling reports and staff members of the competent authority who have the right of access to the information provided by a reporting person comply with the duty of professional secrecy and confidentiality when transmitting the data both inside and outside the competent authority, including where a competent authority opens an investigation or an internal enquiry or engages in enforcement activities in connection with the report.

(78) The regular review of the procedures of competent authorities and the exchange of good practices between them should guarantee that those procedures are adequate and thus serving their purpose.

(79) Persons making a public disclosure should qualify for protection in cases where, despite internal and external reporting, the breach remains unaddressed, for instance in cases where the breach was not appropriately assessed or investigated, or no appropriate remedial action was taken. The appropriateness of the follow-up should be assessed according to objective criteria, linked to the obligation of the competent authorities to assess the accuracy of the allegations and to put an end to any possible breach of Union law. The appropriateness of the follow-up will thus depend on the circumstances of each case and of the nature of the rules that have been breached. In particular, a decision by the authorities that a breach was clearly minor and no further follow-up, other than closure of the procedure, was required could constitute appropriate follow-up pursuant to this Directive.

(80) Persons making a public disclosure directly should also qualify for protection in cases where they have reasonable grounds to believe that there is an imminent or manifest danger to the public interest, or a risk of irreversible damage, including harm to a person's physical integrity.

(81) Persons making a public disclosure directly should also qualify for protection where they have reasonable grounds to believe that in the case of external reporting there is a risk of retaliation or there is a low prospect of the breach being effectively addressed, due to the particular circumstances of the case, such as those where evidence could be concealed or destroyed or where an authority could be in collusion with the perpetrator of the breach or involved in the breach.

(82) Safeguarding the confidentiality of the identity of the reporting person during the reporting process and investigations triggered by the report is an essential ex-ante measure to prevent retaliation. It should only be possible to disclose the identity of the reporting person where that is a necessary and proportionate obligation under Union or national law in the context of investigations by authorities or judicial proceedings, in particular to safeguard the rights of defence of persons concerned. Such an obligation could derive, in particular, from Directive 2012/13/EU of the European Parliament and of the Council[1]. The protection of confidentiality should not apply where the reporting person has intentionally revealed his or her identity in the context of a public disclosure.

[1] Directive 2012/13/EU of the European Parliament and of the Council of 22 May 2012 on the right to information in criminal proceedings (OJ L 142, 1.6.2012, p. 1).

(83) Any processing of personal data carried out pursuant to this Directive, including the exchange or transmission of personal data by the competent authorities, should be undertaken in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council[1] and with Directive (EU) 2016/680 of the European Parliament and of the Council[2]. Any exchange or transmission of information by Union institutions, bodies, offices or agencies should be undertaken in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[3]. Particular regard should be had to the principles relating to processing of personal data set out in Article 5 of Regulation (EU) 2016/679, Article 4 of Directive (EU) 2016/680 and Article 4 of Regulation (EU) 2018/1725, and to the principle of data protection by design and by default laid down in Article 25 of Regulation (EU) 2016/679, Article 20 of Directive (EU) 2016/680 and Articles 27 and 85 of Regulation (EU) 2018/1725.

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1 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).

2 Directive (EU) 2016/680 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 by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, p. 89).

3 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

(84) The procedures provided for in this Directive and related to follow-up on reports of breaches of Union law in the areas falling within its scope serve an important objective of general public interest of the Union and of the Member States, within the meaning of point (e) of Article 23(1) of Regulation (EU) 2016/679, as they aim to enhance the enforcement of Union law and policies in specific areas where breaches can cause serious harm to the public interest. The effective protection of the confidentiality of the identity of reporting persons is necessary for the protection of the rights and freedoms of others, in particular those of the reporting persons, provided for under point (i) of Article 23(1) of Regulation (EU) 2016/679. Member States should ensure that this Directive is effective, including, where necessary, by restricting, by legislative measures, the exercise of certain data protection rights of persons concerned in line with points (e) and (i) of Article 23(1) and Article 23(2) of Regulation (EU) 2016/679 to the extent, and as long as, necessary to prevent and address attempts to hinder reporting or to impede, frustrate or slow down follow-up, in particular investigations, or attempts to find out the identity of the reporting persons.

(85) The effective protection of the confidentiality of the identity of reporting persons is equally necessary for the protection of the rights and freedoms of others, in particular those of the reporting persons, where reports are handled by authorities as defined in point (7) of Article 3 of Directive (EU) 2016/680. Member States should ensure that this Directive is effective, including, where necessary, by restricting, by legislative measures, the exercise of certain data protection rights of persons concerned in line with points (a) and (e) of Article 13(3), points (a) and (e) of Article 15(1), points (a) and (e) of Article 16(4) and Article 31(5) of Directive (EU) 2016/680 to the extent, and as long as, necessary to prevent and address attempts to hinder reporting or to impede, frustrate or slow down follow-up, in particular investigations, or attempts to find out the identity of the reporting persons.

(86) Member States should ensure that there is adequate record-keeping as regards all reports of breaches, that every report is retrievable and that information received through reports can be used as evidence in enforcement actions where appropriate.

(87) Reporting persons should be protected against any form of retaliation, whether direct or indirect, taken, encouraged or tolerated by their employer or customer or recipient of services and by persons working for or acting on behalf of the latter, including colleagues and managers in the same organisation or in other organisations with which the reporting person is in contact in the context of his or her work-related activities

(88) Where retaliation occurs undeterred and unpunished, it has a chilling effect on potential whistleblowers. A clear legal prohibition of retaliation would have an important dissuasive effect, and would be further strengthened by provisions for personal liability and penalties for the perpetrators of retaliation.

(89) Potential whistleblowers who are not sure about how to report or whether they will be protected in the end may be discouraged from reporting. Member States should ensure that relevant and accurate information in that regard is provided in a way that is clear and easily accessible to the general public. Individual, impartial and confidential advice, free of charge, should be available on, for example, whether the information in question is covered by the applicable rules on whistleblower protection, which reporting channel might best be used and which alternative procedures are available in the event that the information is not covered by the applicable rules, so-called 'signposting'. Access to such advice can help to ensure that reports are made through the appropriate channels, in a responsible manner, and that breaches are detected in a timely manner or even prevented. Such advice and information could be provided by an information centre or a single and independent administrative authority. Member States could choose to extend such advice to legal counselling. Where such advice is given to reporting persons by civil society organisations which are bound by a duty of maintaining the confidential nature of the information received, Member States should ensure that such organisations do not suffer retaliation, for instance in the form of economic prejudice through a restriction on their access to funding or blacklisting that could impede the proper functioning of the organisation.

(90) Competent authorities should provide reporting persons with the support necessary for them to access protection effectively. In particular, they should provide proof or other documentation required to confirm to other authorities or courts that external reporting has taken place. Under certain national frameworks and in certain cases, reporting persons may benefit from forms of certification of the fact that they meet the conditions of the applicable rules. Notwithstanding such possibilities, they should have effective access to judicial review, whereby it is for the courts to decide, based on all the individual circumstances of the case, whether they meet the conditions of the applicable rules.

(91) It should not be possible to rely on individuals' legal or contractual obligations, such as loyalty clauses in contracts or confidentiality or non-disclosure agreements, so as to preclude reporting, to deny protection or to penalise reporting persons for having reported information on breaches or made a public disclosure where providing the information falling within the scope of such clauses and agreements is necessary for revealing the breach. Where those conditions are met, reporting persons should not incur any kind of liability, be it civil, criminal, administrative or employment-related. It is appropriate that there be protection from liability for the reporting or public disclosure under this Directive of information in respect of which the reporting person had reasonable grounds to believe that reporting or public disclosure was necessary to reveal a breach pursuant to this Directive. Such protection should not extend to superfluous information that the person revealed without having such reasonable grounds.

(92) Where reporting persons lawfully acquire or obtain access to the information on breaches reported or the documents containing that information, they should enjoy immunity from liability. This should apply both in cases where reporting persons reveal the content of documents to which they have lawful access as well as in cases where they make copies of such documents or remove them from the premises of the organisation where they are employed, in breach of contractual or other clauses stipulating that the relevant documents are the property of the organisation. The reporting persons should also enjoy immunity from liability in cases where the acquisition of or access to the relevant information or documents raises an issue of civil, administrative or labour-related liability. Examples would be cases where the reporting persons acquired the information by accessing the emails of a co-worker or files which they normally do not use within the scope of their work, by taking pictures of the premises of the organisation or by accessing locations they do not usually have access to. Where the reporting persons acquired or obtained access to the relevant information or documents by committing a criminal offence, such as physical trespassing or hacking, their criminal liability should remain governed by the applicable national law, without prejudice to the protection granted under Article 21(7) of this Directive. Similarly, any other possible liability of the reporting persons arising from acts or omissions which are unrelated to the reporting or are not necessary for revealing a breach pursuant to this Directive should remain governed by the applicable Union or national law. In those cases, it should be for the national courts to assess the liability of the reporting persons in the light of all relevant factual information and taking into account the individual circumstances of the case, including the necessity and proportionality of the act or omission in relation to the report or public disclosure.

(93) Retaliation is likely to be presented as being justified on grounds other than the reporting and it can be very difficult for reporting persons to prove the link between the reporting and the retaliation, whilst the perpetrators of retaliation may have greater power and resources to document the action taken and the reasoning. Therefore, once the reporting person demonstrates prima facie that he or she reported breaches or made a public disclosure in accordance with this Directive and suffered a detriment, the burden of proof should shift to the person who took the detrimental action, who should then be required to demonstrate that the action taken was not linked in any way to the reporting or the public disclosure.

(94) Beyond an explicit prohibition of retaliation provided in law, it is crucial that reporting persons who do suffer retaliation have access to legal remedies and compensation. The appropriate remedy in each case should be determined by the kind of retaliation suffered, and the damage caused in such cases should be compensated in full in accordance with national law. The appropriate remedy could take the form of actions for reinstatement, for instance, in the event of dismissal, transfer or demotion, or of withholding of training or promotion, or for restoration of a cancelled permit, licence or contract; compensation for actual and future financial losses, for example for lost past wages, but also for future loss of income, costs linked to a change of occupation; and compensation for other economic damage, such as legal expenses and costs of medical treatment, and for intangible damage such as pain and suffering.

(95) While the types of legal action may vary between legal systems, they should ensure that compensation or reparation is real and effective, in a way which is proportionate to the detriment suffered and is dissuasive. Of relevance in this context are the Principles of the European Pillar of Social Rights, in particular Principle 7 according to which 'Prior to any dismissal, workers have the right to be informed of the reasons and be granted a reasonable period of notice. They have the right to access to effective and impartial dispute resolution and, in case of unjustified dismissal, a right to redress, including adequate compensation.'. The remedies established at national level should not discourage potential future whistleblowers. For instance, providing for compensation as an alternative to reinstatement in the event of dismissal might give rise to a systematic practice, in particular by larger organisations, thus having a dissuasive effect on future whistleblowers.

(96) Of particular importance for reporting persons are interim remedies pending the resolution of legal proceedings that can be protracted. Particularly, actions of interim relief, as provided for under national law, should also be available to reporting persons in order to stop threats, attempts or continuing acts of retaliation, such as harassment or to prevent forms of retaliation, such as dismissal, which might be difficult to reverse after the lapse of lengthy periods and which can ruin the individual financially, a perspective which can seriously discourage potential whistleblowers.

(97) Action taken against reporting persons outside the work-related context, through proceedings, for instance, related to defamation, breach of copyright, trade secrets, confidentiality and personal data protection, can also pose a serious deterrent to whistleblowing. In such proceedings, reporting persons should be able to rely on having reported breaches or made a public disclosure in accordance with this Directive as a defence, provided that the information reported or publicly disclosed was necessary to reveal the breach. In such cases, the person initiating the proceedings should carry the burden of proving that the reporting person does not meet the conditions laid down by this Directive.

(98) Directive (EU) 2016/943 of the European Parliament and of the Council[1] lays down rules to ensure a sufficient and consistent level of civil redress in the event of unlawful acquisition, use or disclosure of a trade secret. However, it also provides that the acquisition, use or disclosure of a trade secret is to be considered lawful to the extent that it is allowed by Union law. Persons who disclose trade secrets acquired in a work-related context should only benefit from the protection granted by this Directive, including in terms of not incurring civil liability, provided that they meet the conditions laid down by this Directive, including that the disclosure was necessary to reveal a breach falling within the material scope of this Directive. Where those conditions are met, disclosures of trade secrets are to be considered allowed by Union law within the meaning of Article 3(2) of Directive (EU) 2016/943. Moreover, both Directives should be considered as being complementary and the civil redress measures, procedures and remedies as well as exemptions provided for in Directive (EU) 2016/943 should remain applicable for all disclosures of trade secrets falling outside the scope of this Directive. Competent authorities that receive information on breaches that includes trade secrets should ensure that they are not used or disclosed for purposes going beyond what is necessary for proper follow-up of the reports.

[1] Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

(99) A significant cost for reporting persons contesting retaliation measures taken against them in legal proceedings can be the relevant legal fees. Although they could recover such fees at the end of the proceedings, they might not be able to pay those fees if charged at the outset of proceedings, especially if they are unemployed and blacklisted. Assistance for criminal legal proceedings, particularly where the reporting persons meet the conditions of Directive (EU) 2016/1919 of the European Parliament and of the Council[1], and, more generally, support to those who are in serious financial need might be key, in certain cases, for the effective enforcement of their rights to protection.

(100) The rights of the person concerned should be protected in order to avoid reputational damage or other negative consequences. Furthermore, the rights of defence and access to remedies of the person concerned should be fully respected at every stage of the procedure following the report, in accordance with Articles 47 and 48 of the Charter. Member States should protect the confidentiality of the identity of the person concerned and ensure the rights of defence including the right of access to the file, the right to be heard and the right to seek effective remedy against a decision concerning the person concerned under the applicable procedures set out in national law in the context of investigations or subsequent judicial proceedings.

[1] Directive (EU) 2016/1919 of the European Parliament and of the Council of 26 October 2016 on legal aid for suspects and accused persons in criminal proceedings and for requested persons in European arrest warrant proceedings (OJ L 297, 4.11.2016, p. 1).

(101) Any person who suffers prejudice, whether directly or indirectly, as a consequence of the reporting or public disclosure of inaccurate or misleading information should retain the protection and the remedies available to him or her under the rules of general national law. Where such inaccurate or misleading information was reported or publicly disclosed deliberately and knowingly, the persons concerned should be entitled to compensation in accordance with national law.

(102) Criminal, civil or administrative penalties are necessary to ensure the effectiveness of the rules on whistleblower protection. Penalties against those who take retaliatory or other adverse actions against reporting persons can discourage further such actions. Penalties against persons who report or publicly disclose information on breaches which is demonstrated to be knowingly false are also necessary to deter further malicious reporting and preserve the credibility of the system. The proportionality of such penalties should ensure that they do not have a dissuasive effect on potential whistleblowers.

(103) Any decision taken by authorities adversely affecting the rights granted by this Directive, in particular decisions by which competent authorities decide to close the procedure regarding a reported breach on account of it being clearly minor or on account of the report being repetitive, or decide that a particular report does not deserve priority treatment, is subject to judicial review in accordance with Article 47 of the Charter.

(104) This Directive introduces minimum standards and it should be possible for Member States to introduce or maintain provisions which are more favourable to the reporting person, provided that such provisions do not interfere with the measures for the protection of persons concerned. The transposition of this Directive should, under no circumstances, provide grounds for reducing the level of protection already granted to reporting persons under national law in the areas to which it applies.

(105) In accordance with Article 26(2) TFEU, the internal market needs to comprise an area without internal frontiers in which the free movement of goods and services is ensured. The internal market should provide Union citizens with added value in the form of better quality and safety of goods and services, ensuring high standards of public health and environmental protection as well as free movement of personal data. Thus, Article 114 TFEU is the appropriate legal basis to adopt the measures necessary for the establishment and functioning of the internal market. In addition to Article 114 TFEU, this Directive should have additional specific legal bases in order to cover the fields that rely on Article 16, Article 43(2), Article 50, Article 53(1), Articles 91 and 100, Article 168(4), Article 169, Article 192(1) and Article 325(4) TFEU and Article 31 of the Euratom Treaty for the adoption of Union measures.

(106) The material scope of this Directive is based on the identification of areas where the introduction of whistleblower protection appears justified and necessary on the basis of currently available evidence. Such material scope could be extended to further areas or Union acts, if that proves necessary as a means of strengthening their enforcement in the light of evidence that may come to the fore in the future, or on the basis of the evaluation of the way in which this Directive has functioned.

(107) Where future legislative acts relevant to the policy areas covered by this Directive are adopted, they should specify, where appropriate, that this Directive applies. Where necessary, the material scope of this Directive should be adapted and the Annex should be amended accordingly.

(108) Since the objective of this Directive, namely to strengthen enforcement in certain policy areas and as regards acts where breaches of Union law can cause serious harm to the public interest, through effective whistleblower protection, cannot be sufficiently achieved by the Member States acting alone or in an uncoordinated manner, but can rather be better achieved at Union level by laying down common minimum standards for whistleblower protection, and given that only Union action can provide coherence and align the existing Union rules on whistleblower protection, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(109) This Directive respects fundamental rights and the principles recognised in particular by the Charter, in particular Article 11 thereof. Accordingly, it is essential that this Directive be implemented in accordance with those rights and principles by ensuring full respect for, inter alia, freedom of expression and information, the right to protection of personal data, the freedom to conduct a business, the right to a high level of consumer protection, the right to a high level of human health protection, the right to a high level of environmental protection, the right to good administration, the right to an effective remedy and the rights of defence.

(110) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I
SCOPE, DEFINITIONS AND CONDITIONS FOR PROTECTION

Article 1

Purpose

The purpose of this Directive is to enhance the enforcement of Union law and policies in specific areas by laying down common minimum standards providing for a high level of protection of persons reporting breaches of Union law.

Article 2

Material scope

1. This Directive lays down common minimum standards for the protection of persons reporting the following breaches of Union law:

   (a) breaches falling within the scope of the Union acts set out in the Annex that concern the following areas:

      (i) public procurement;

      (ii) financial services, products and markets, and prevention of money laundering and terrorist financing;

(iii) product safety and compliance;

(iv) transport safety;

(v) protection of the environment;

(vi) radiation protection and nuclear safety;

(vii) food and feed safety, animal health and welfare;

(viii) public health;

(ix) consumer protection;

(x) protection of privacy and personal data, and security of network and information systems;

(b) breaches affecting the financial interests of the Union as referred to in Article 325 TFEU and as further specified in relevant Union measures;

(c) breaches relating to the internal market, as referred to in Article 26(2) TFEU, including breaches of Union competition and State aid rules, as well as breaches relating to the internal market in relation to acts which breach the rules of corporate tax or to arrangements the purpose of which is to obtain a tax advantage that defeats the object or purpose of the applicable corporate tax law.

2. This Directive is without prejudice to the power of Member States to extend protection under national law as regards areas or acts not covered by paragraph 1.

Article 3

Relationship with other Union acts and national provisions

1. Where specific rules on the reporting of breaches are provided for in the sector-specific Union acts listed in Part II of the Annex, those rules shall apply. The provisions of this Directive shall be applicable to the extent that a matter is not mandatorily regulated in those sector-specific Union acts.

2. This Directive shall not affect the responsibility of Member States to ensure national security or their power to protect their essential security interests. In particular, it shall not apply to reports of breaches of the procurement rules involving defence or security aspects unless they are covered by the relevant acts of the Union.

3. This Directive shall not affect the application of Union or national law relating to any of the following:

   (a) the protection of classified information;

   (b) the protection of legal and medical professional privilege;

   (c) the secrecy of judicial deliberations;

   (d) rules on criminal procedure.

4. This Directive shall not affect national rules on the exercise by workers of their rights to consult their representatives or trade unions, and on protection against any unjustified detrimental measure prompted by such consultations as well as on the autonomy of the social partners and their right to enter into collective agreements. This is without prejudice to the level of protection granted by this Directive.

Article 4

Personal scope

1. This Directive shall apply to reporting persons working in the private or public sector who acquired information on breaches in a work-related context including, at least, the following:

   (a) persons having the status of worker, within the meaning of Article 45(1) TFEU, including civil servants;

   (b) persons having self-employed status, within the meaning of Article 49 TFEU;

   (c) shareholders and persons belonging to the administrative, management or supervisory body of an undertaking, including non-executive members, as well as volunteers and paid or unpaid trainees;

   (d) any persons working under the supervision and direction of contractors, subcontractors and suppliers.

2. This Directive shall also apply to reporting persons where they report or publicly disclose information on breaches acquired in a work-based relationship which has since ended.

3. This Directive shall also apply to reporting persons whose work-based relationship is yet to begin in cases where information on breaches has been acquired during the recruitment process or other pre-contractual negotiations.

4. The measures for the protection of reporting persons set out in Chapter VI shall also apply, where relevant, to:

(a) facilitators;

(b) third persons who are connected with the reporting persons and who could suffer retaliation in a work-related context, such as colleagues or relatives of the reporting persons; and

(c) legal entities that the reporting persons own, work for or are otherwise connected with in a work-related context.

Article 5

Definitions

For the purposes of this Directive, the following definitions apply:

(1) 'breaches' means acts or omissions that:

(i) are unlawful and relate to the Union acts and areas falling within the material scope referred to in Article 2; or

(ii) defeat the object or the purpose of the rules in the Union acts and areas falling within the material scope referred to in Article 2;

(2) 'information on breaches' means information, including reasonable suspicions, about actual or potential breaches, which occurred or are very likely to occur in the organisation in which the reporting person works or has worked or in another organisation with which the reporting person is or was in contact through his or her work, and about attempts to conceal such breaches;

(3) 'report' or 'to report' means, the oral or written communication of information on breaches;

(4) 'internal reporting' means the oral or written communication of information on breaches within a legal entity in the private or public sector;

(5) ‘external reporting’ means the oral or written communication of information on breaches to the competent authorities;

(6) ‘public disclosure’ or ‘to publicly disclose’ means the making of information on breaches available in the public domain;

(7) ‘reporting person’ means a natural person who reports or publicly discloses information on breaches acquired in the context of his or her work-related activities;

(8) ‘facilitator’ means a natural person who assists a reporting person in the reporting process in a work-related context, and whose assistance should be confidential;

(9) ‘work-related context’ means current or past work activities in the public or private sector through which, irrespective of the nature of those activities, persons acquire information on breaches and within which those persons could suffer retaliation if they reported such information;

(10) ‘person concerned’ means a natural or legal person who is referred to in the report or public disclosure as a person to whom the breach is attributed or with whom that person is associated;

(11) ‘retaliation’ means any direct or indirect act or omission which occurs in a work-related context, is prompted by internal or external reporting or by public disclosure, and which causes or may cause unjustified detriment to the reporting person;

(12) ‘follow-up’ means any action taken by the recipient of a report or any competent authority, to assess the accuracy of the allegations made in the report and, where relevant, to address the breach reported, including through actions such as an internal enquiry, an investigation, prosecution, an action for recovery of funds, or the closure of the procedure;

(13) ‘feedback’ means the provision to the reporting person of information on the action envisaged or taken as follow-up and on the grounds for such follow-up;

(14) ‘competent authority’ means any national authority designated to receive reports in accordance with Chapter III and give feedback to the reporting person, and/or designated to carry out the duties provided for in this Directive, in particular as regards follow-up.

Article 6

Conditions for protection of reporting persons

1. Reporting persons shall qualify for protection under this Directive provided that:

(a) they had reasonable grounds to believe that the information on breaches reported was true at the time of reporting and that such information fell within the scope of this Directive; and

(b) they reported either internally in accordance with Article 7 or externally in accordance with Article 10, or made a public disclosure in accordance with Article 15.

2. Without prejudice to existing obligations to provide for anonymous reporting by virtue of Union law, this Directive does not affect the power of Member States to decide whether legal entities in the private or public sector and competent authorities are required to accept and follow up on anonymous reports of breaches.

3. Persons who reported or publicly disclosed information on breaches anonymously, but who are subsequently identified and suffer retaliation, shall nonetheless qualify for the protection provided for under Chapter VI, provided that they meet the conditions laid down in paragraph 1.

4. Persons reporting to relevant institutions, bodies, offices or agencies of the Union breaches falling within the scope of this Directive shall qualify for protection as laid down in this Directive under the same conditions as persons who report externally.

CHAPTER II
INTERNAL REPORTING AND FOLLOW-UP

Article 7

Reporting through internal reporting channels

1. As a general principle and without prejudice to Articles 10 and 15, information on breaches may be reported through the internal reporting channels and procedures provided for in this Chapter.

2. Member States shall encourage reporting through internal reporting channels before reporting through external reporting channels, where the breach can be addressed effectively internally and where the reporting person considers that there is no risk of retaliation.

3. Appropriate information relating to the use of internal reporting channels referred to in paragraph 2 shall be provided in the context of the information given by legal entities in the private and public sector pursuant to point (g) of Article 9(1), and by competent authorities pursuant to point (a) of Article 12(4) and Article 13.

Article 8

Obligation to establish internal reporting channels

1. Member States shall ensure that legal entities in the private and public sector establish channels and procedures for internal reporting and for follow-up, following consultation and in agreement with the social partners where provided for by national law.

2. The channels and procedures referred to in paragraph 1 of this Article shall enable the entity's workers to report information on breaches. They may enable other persons, referred to in points (b), (c) and (d) of Article 4(1) and Article 4(2), who are in contact with the entity in the context of their work-related activities to also report information on breaches.

3. Paragraph 1 shall apply to legal entities in the private sector with 50 or more workers.

4. The threshold laid down in paragraph 3 shall not apply to the entities falling within the scope of Union acts referred to in Parts I.B and II of the Annex.

5. Reporting channels may be operated internally by a person or department designated for that purpose or provided externally by a third party. The safeguards and requirements referred to in Article 9(1) shall also apply to entrusted third parties operating the reporting channel for a legal entity in the private sector.

6. Legal entities in the private sector with 50 to 249 workers may share resources as regards the receipt of reports and any investigation to be carried out. This shall be without prejudice to the obligations imposed upon such entities by this Directive to maintain confidentiality, to give feedback, and to address the reported breach.

7. Following an appropriate risk assessment taking into account the nature of the activities of the entities and the ensuing level of risk for, in particular, the environment and public health, Member States may require legal entities in the private sector with fewer than 50 workers to establish internal reporting channels and procedures in accordance with Chapter II.

8. Member States shall notify the Commission of any decision they take to require legal entities in the private sector to establish internal reporting channels pursuant to paragraph 7. That notification shall include the reasons for the decision and the criteria used in the risk assessment referred to in paragraph 7. The Commission shall communicate that decision to the other Member States.

9. Paragraph 1 shall apply to all legal entities in the public sector, including any entity owned or controlled by such entities.

Member States may exempt from the obligation referred to in paragraph 1 municipalities with fewer than 10 000 inhabitants or fewer than 50 workers, or other entities referred to in the first subparagraph of this paragraph with fewer than 50 workers.

Member States may provide that internal reporting channels can be shared between municipalities or operated by joint municipal authorities in accordance with national law, provided that the shared internal reporting channels are distinct from and autonomous in relation to the relevant external reporting channels.

Article 9

Procedures for internal reporting and follow-up

1. The procedures for internal reporting and for follow-up as referred to in Article 8 shall include the following:

(a) channels for receiving the reports which are designed, established and operated in a secure manner that ensures that the confidentiality of the identity of the reporting person and any third party mentioned in the report is protected, and prevents access thereto by non-authorised staff members;

(b) acknowledgment of receipt of the report to the reporting person within seven days of that receipt;

(c) the designation of an impartial person or department competent for following-up on the reports which may be the same person or department as the one that receives the reports and which will maintain communication with the reporting person and, where necessary, ask for further information from and provide feedback to that reporting person;

(d) diligent follow-up by the designated person or department referred to in point (c);

(e) diligent follow-up, where provided for in national law, as regards anonymous reporting;

(f) a reasonable timeframe to provide feedback, not exceeding three months from the acknowledgment of receipt or, if no acknowledgement was sent to the reporting person, three months from the expiry of the seven-day period after the report was made;

(g) provision of clear and easily accessible information regarding the procedures for reporting externally to competent authorities pursuant to Article 10 and, where relevant, to institutions, bodies, offices or agencies of the Union.

2. The channels provided for in point (a) of paragraph 1 shall enable reporting in writing or orally, or both. Oral reporting shall be possible by telephone or through other voice messaging systems, and, upon request by the reporting person, by means of a physical meeting within a reasonable timeframe.

CHAPTER III
EXTERNAL REPORTING AND FOLLOW-UP

Article 10

Reporting through external reporting channels

Without prejudice to point (b) of Article 15(1), reporting persons shall report information on breaches using the channels and procedures referred to in Articles 11 and 12, after having first reported through internal reporting channels, or by directly reporting through external reporting channels.

Article 11

Obligation to establish external reporting channels and to follow up on reports

1. Member States shall designate the authorities competent to receive, give feedback and follow up on reports, and shall provide them with adequate resources.

2. Member States shall ensure that the competent authorities:

   (a) establish independent and autonomous external reporting channels, for receiving and handling information on breaches;

(b) promptly, and in any event within seven days of receipt of the report, acknowledge that receipt unless the reporting person explicitly requested otherwise or the competent authority reasonably believes that acknowledging receipt of the report would jeopardise the protection of the reporting person's identity;

(c) diligently follow up on the reports;

(d) provide feedback to the reporting person within a reasonable timeframe not exceeding three months, or six months in duly justified cases;

(e) communicate to the reporting person the final outcome of investigations triggered by the report, in accordance with procedures provided for under national law;

(f) transmit in due time the information contained in the report to competent institutions, bodies, offices or agencies of the Union, as appropriate, for further investigation, where provided for under Union or national law.

3. Member States may provide that competent authorities, after having duly assessed the matter, can decide that a reported breach is clearly minor and does not require further follow-up pursuant to this Directive, other than closure of the procedure. This shall not affect other obligations or other applicable procedures to address the reported breach, or the protection granted by this Directive in relation to internal or external reporting. In such a case, the competent authorities shall notify the reporting person of their decision and the reasons therefor.

4. Member States may provide that competent authorities can decide to close procedures regarding repetitive reports which do not contain any meaningful new information on breaches compared to a past report in respect of which the relevant procedures were concluded, unless new legal or factual circumstances justify a different follow-up. In such a case, the competent authorities shall notify the reporting person of their decision and the reasons therefor.

5. Member States may provide that, in the event of high inflows of reports, competent authorities may deal with reports of serious breaches or breaches of essential provisions falling within the scope of this Directive as a matter of priority, without prejudice to the timeframe as set out in point (d) of paragraph 2.

6. Member States shall ensure that any authority which has received a report but does not have the competence to address the breach reported transmits it to the competent authority, within a reasonable time, in a secure manner, and that the reporting person is informed, without delay, of such a transmission.

Article 12

Design of external reporting channels

1. External reporting channels shall be considered independent and autonomous, if they meet all of the following criteria:

   (a) they are designed, established and operated in a manner that ensures the completeness, integrity and confidentiality of the information and prevents access thereto by non-authorised staff members of the competent authority;

   (b) they enable the durable storage of information in accordance with Article 18 to allow further investigations to be carried out.

2. The external reporting channels shall enable reporting in writing and orally. Oral reporting shall be possible by telephone or through other voice messaging systems and, upon request by the reporting person, by means of a physical meeting within a reasonable timeframe.

3. Competent authorities shall ensure that, where a report is received through channels other than the reporting channels referred to in paragraphs 1 and 2 or by staff members other than those responsible for handling reports, the staff members who receive it are prohibited from disclosing any information that might identify the reporting person or the person concerned, and that they promptly forward the report without modification to the staff members responsible for handling reports.

4. Member States shall ensure that competent authorities designate staff members responsible for handling reports, and in particular for:

(a) providing any interested person with information on the procedures for reporting;

(b) receiving and following up on reports;

(c) maintaining contact with the reporting person for the purpose of providing feedback and requesting further information where necessary.

5. The staff members referred to in paragraph 4 shall receive specific training for the purposes of handling reports.

Article 13

Information regarding the receipt of reports and their follow-up

Member States shall ensure that competent authorities publish on their websites in a separate, easily identifiable and accessible section at least the following information:

(a) the conditions for qualifying for protection under this Directive;

(b) the contact details for the external reporting channels as provided for under Article 12, in particular the electronic and postal addresses, and the phone numbers for such channels, indicating whether the phone conversations are recorded;

(c) the procedures applicable to the reporting of breaches, including the manner in which the competent authority may request the reporting person to clarify the information reported or to provide additional information, the timeframe for providing feedback and the type and content of such feedback;

(d) the confidentiality regime applicable to reports, and in particular the information in relation to the processing of personal data in accordance with Article 17 of this Directive, Articles 5 and 13 of Regulation (EU) 2016/679, Article 13 of Directive (EU) 2016/680 and Article 15 of Regulation (EU) 2018/1725, as applicable;

(e) the nature of the follow-up to be given to reports;

(f) the remedies and procedures for protection against retaliation and the availability of confidential advice for persons contemplating reporting;

(g) a statement clearly explaining the conditions under which persons reporting to the competent authority are protected from incurring liability for a breach of confidentiality pursuant to Article 21(2); and

(h) contact details of the information centre or of the single independent administrative authority as provided for in Article 20(3) where applicable.

Article 14

Review of the procedures by competent authorities

Member States shall ensure that competent authorities review their procedures for receiving reports, and their follow-up, regularly, and at least once every three years. In reviewing such procedures, competent authorities shall take account of their experience as well as that of other competent authorities and adapt their procedures accordingly.

CHAPTER IV
PUBLIC DISCLOSURES

Article 15

Public disclosures

1. A person who makes a public disclosure shall qualify for protection under this Directive if any of the following conditions is fulfilled:

   (a) the person first reported internally and externally, or directly externally in accordance with Chapters II and III, but no appropriate action was taken in response to the report within the timeframe referred to in point (f) of Article 9(1) or point (d) of Article 11(2); or

(b) the person has reasonable grounds to believe that:

(i) the breach may constitute an imminent or manifest danger to the public interest, such as where there is an emergency situation or a risk of irreversible damage; or

(ii) in the case of external reporting, there is a risk of retaliation or there is a low prospect of the breach being effectively addressed, due to the particular circumstances of the case, such as those where evidence may be concealed or destroyed or where an authority may be in collusion with the perpetrator of the breach or involved in the breach.

2. This Article shall not apply to cases where a person directly discloses information to the press pursuant to specific national provisions establishing a system of protection relating to freedom of expression and information.

CHAPTER V
PROVISIONS APPLICABLE TO INTERNAL AND EXTERNAL REPORTING

Article 16

Duty of confidentiality

1. Member States shall ensure that the identity of the reporting person is not disclosed to anyone beyond the authorised staff members competent to receive or follow up on reports, without the explicit consent of that person. This shall also apply to any other information from which the identity of the reporting person may be directly or indirectly deduced.

2. By way of derogation from paragraph 1, the identity of the reporting person and any other information referred to in paragraph 1 may be disclosed only where this is a necessary and proportionate obligation imposed by Union or national law in the context of investigations by national authorities or judicial proceedings, including with a view to safeguarding the rights of defence of the person concerned.

3. Disclosures made pursuant to the derogation provided for in paragraph 2 shall be subject to appropriate safeguards under the applicable Union and national rules. In particular, reporting persons shall be informed before their identity is disclosed, unless such information would jeopardise the related investigations or judicial proceedings. When informing the reporting persons, the competent authority shall send them an explanation in writing of the reasons for the disclosure of the confidential data concerned.

4. Member States shall ensure that competent authorities that receive information on breaches that includes trade secrets do not use or disclose those trade secrets for purposes going beyond what is necessary for proper follow-up.

Article 17

Processing of personal data

Any processing of personal data carried out pursuant to this Directive, including the exchange or transmission of personal data by the competent authorities, shall be carried out in accordance with Regulation (EU) 2016/679 and Directive (EU) 2016/680. Any exchange or transmission of information by Union institutions, bodies, offices or agencies shall be undertaken in accordance with Regulation (EU) 2018/1725.

Personal data which are manifestly not relevant for the handling of a specific report shall not be collected or, if accidentally collected, shall be deleted without undue delay.

Article 18

Record keeping of the reports

1. Member States shall ensure that legal entities in the private and public sector and competent authorities keep records of every report received, in compliance with the confidentiality requirements provided for in Article 16. Reports shall be stored for no longer than it is necessary and proportionate in order to comply with the requirements imposed by this Directive, or other requirements imposed by Union or national law.

2. Where a recorded telephone line or another recorded voice messaging system is used for reporting, subject to the consent of the reporting person, legal entities in the private and public sector and competent authorities shall have the right to document the oral reporting in one of the following ways:

   (a) by making a recording of the conversation in a durable and retrievable form; or

   (b) through a complete and accurate transcript of the conversation prepared by the staff members responsible for handling the report.

   Legal entities in the private and public sector and competent authorities shall offer the reporting person the opportunity to check, rectify and agree the transcript of the call by signing it.

3. Where an unrecorded telephone line or another unrecorded voice messaging system is used for reporting, legal entities in the private and public sector and competent authorities shall have the right to document the oral reporting in the form of accurate minutes of the conversation written by the staff member responsible for handling the report. Legal entities in the private and public sector and competent authorities shall offer the reporting person the opportunity to check, rectify and agree the minutes of the conversation by signing them.

4. Where a person requests a meeting with the staff members of legal entities in the private and public sector or of competent authorities for reporting purposes pursuant to Articles 9(2) and 12(2), legal entities in the private and public sector and competent authorities shall ensure, subject to the consent of the reporting person, that complete and accurate records of the meeting are kept in a durable and retrievable form.

Legal entities in the private and public sector and competent authorities shall have the right to document the meeting in one of the following ways:

(a) by making a recording of the conversation in a durable and retrievable form; or

(b) through accurate minutes of the meeting prepared by the staff members responsible for handling the report.

Legal entities in the private and public sector and competent authorities shall offer the reporting person the opportunity to check, rectify and agree the minutes of the meeting by signing them.

CHAPTER VI
PROTECTION MEASURES

Article 19

Prohibition of retaliation

Member States shall take the necessary measures to prohibit any form of retaliation against persons referred to in Article 4, including threats of retaliation and attempts of retaliation including in particular in the form of:

(a) suspension, lay-off, dismissal or equivalent measures;

(b) demotion or withholding of promotion;

(c) transfer of duties, change of location of place of work, reduction in wages, change in working hours;

(d) withholding of training;

(e) a negative performance assessment or employment reference;

(f) imposition or administering of any disciplinary measure, reprimand or other penalty, including a financial penalty;

(g) coercion, intimidation, harassment or ostracism;

(h) discrimination, disadvantageous or unfair treatment;

(i) failure to convert a temporary employment contract into a permanent one, where the worker had legitimate expectations that he or she would be offered permanent employment;

(j) failure to renew, or early termination of, a temporary employment contract;

(k) harm, including to the person's reputation, particularly in social media, or financial loss, including loss of business and loss of income;

(l) blacklisting on the basis of a sector or industry-wide informal or formal agreement, which may entail that the person will not, in the future, find employment in the sector or industry;

(m) early termination or cancellation of a contract for goods or services;

(n) cancellation of a licence or permit;

(o) psychiatric or medical referrals.

Article 20

Measures of support

1. Member States shall ensure that persons referred to in Article 4 have access, as appropriate, to support measures, in particular the following:

   (a) comprehensive and independent information and advice, which is easily accessible to the public and free of charge, on procedures and remedies available, on protection against retaliation, and on the rights of the person concerned;

   (b) effective assistance from competent authorities before any relevant authority involved in their protection against retaliation, including, where provided for under national law, certification of the fact that they qualify for protection under this Directive; and

   (c) legal aid in criminal and in cross-border civil proceedings in accordance with Directive (EU) 2016/1919 and Directive 2008/52/EC of the European Parliament and of the Council[1], and, in accordance with national law, legal aid in further proceedings and legal counselling or other legal assistance.

2. Member States may provide for financial assistance and support measures, including psychological support, for reporting persons in the framework of legal proceedings.

[1] Directive 2008/52/EC of the European Parliament and of the Council of 21 May 2008 on certain aspects of mediation in civil and commercial matters (OJ L 136, 24.5.2008, p. 3).

3. The support measures referred to in this Article may be provided, as appropriate, by an information centre or a single and clearly identified independent administrative authority.

Article 21

Measures for protection against retaliation

1. Member States shall take the necessary measures to ensure that persons referred to in Article 4 are protected against retaliation. Such measures shall include, in particular, those set out in paragraphs 2 to 8 of this Article.

2. Without prejudice to Article 3(2) and (3), where persons report information on breaches or make a public disclosure in accordance with this Directive they shall not be considered to have breached any restriction on disclosure of information and shall not incur liability of any kind in respect of such a report or public disclosure provided that they had reasonable grounds to believe that the reporting or public disclosure of such information was necessary for revealing a breach pursuant to this Directive.

3. Reporting persons shall not incur liability in respect of the acquisition of or access to the information which is reported or publicly disclosed, provided that such acquisition or access did not constitute a self-standing criminal offence. In the event of the acquisition or access constituting a self-standing criminal offence, criminal liability shall continue to be governed by applicable national law.

4. Any other possible liability of reporting persons arising from acts or omissions which are unrelated to the reporting or public disclosure or which are not necessary for revealing a breach pursuant to this Directive shall continue to be governed by applicable Union or national law.

5. In proceedings before a court or other authority relating to a detriment suffered by the reporting person, and subject to that person establishing that he or she reported or made a public disclosure and suffered a detriment, it shall be presumed that the detriment was made in retaliation for the report or the public disclosure. In such cases, it shall be for the person who has taken the detrimental measure to prove that that measure was based on duly justified grounds.

6. Persons referred to in Article 4 shall have access to remedial measures against retaliation as appropriate, including interim relief pending the resolution of legal proceedings, in accordance with national law.

7. In legal proceedings, including for defamation, breach of copyright, breach of secrecy, breach of data protection rules, disclosure of trade secrets, or for compensation claims based on private, public, or on collective labour law, persons referred to in Article 4 shall not incur liability of any kind as a result of reports or public disclosures under this Directive. Those persons shall have the right to rely on that reporting or public disclosure to seek dismissal of the case, provided that they had reasonable grounds to believe that the reporting or public disclosure was necessary for revealing a breach, pursuant to this Directive.

Where a person reports or publicly discloses information on breaches falling within the scope of this Directive, and that information includes trade secrets, and where that person meets the conditions of this Directive, such reporting or public disclosure shall be considered lawful under the conditions of Article 3(2) of the Directive (EU) 2016/943.

8. Member States shall take the necessary measures to ensure that remedies and full compensation are provided for damage suffered by persons referred to in Article 4 in accordance with national law.

Article 22

Measures for the protection of persons concerned

1. Member States shall ensure, in accordance with the Charter, that persons concerned fully enjoy the right to an effective remedy and to a fair trial, as well as the presumption of innocence and the rights of defence, including the right to be heard and the right to access their file.

2. Competent authorities shall ensure, in accordance with national law, that the identity of persons concerned is protected for as long as investigations triggered by the report or the public disclosure are ongoing.

3. The rules set out in Articles 12, 17 and 18 as regards the protection of the identity of reporting persons shall also apply to the protection of the identity of persons concerned.

Article 23

Penalties

1. Member States shall provide for effective, proportionate and dissuasive penalties applicable to natural or legal persons that:

   (a) hinder or attempt to hinder reporting;

   (b) retaliate against persons referred to in Article 4;

   (c) bring vexatious proceedings against persons referred to in Article 4;

   (d) breach the duty of maintaining the confidentiality of the identity of reporting persons, as referred to in Article 16.

2. Member States shall provide for effective, proportionate and dissuasive penalties applicable in respect of reporting persons where it is established that they knowingly reported or publicly disclosed false information. Member States shall also provide for measures for compensating damage resulting from such reporting or public disclosures in accordance with national law.

Article 24

No Waiver of rights and remedies

Member States shall ensure that the rights and remedies provided for under this Directive cannot be waived or limited by any agreement, policy, form or condition of employment, including a pre-dispute arbitration agreement.

CHAPTER VII
FINAL PROVISIONS

Article 25

More favourable treatment and non-regression clause

1. Member States may introduce or retain provisions more favourable to the rights of reporting persons than those set out in this Directive, without prejudice to Article 22 and Article 23(2).

2. The implementation of this Directive shall under no circumstances constitute grounds for a reduction in the level of protection already afforded by Member States in the areas covered by this Directive.

Article 26

Transposition and transitional period

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by … [two years after the date of entry into force of this Directive].

2. By way of derogation from paragraph 1, as regards legal entities in the private sector with 50 to 249 workers, Member States shall by … [four years after the date of entry into force of this Directive] bring into force the laws, regulations and administrative provisions necessary to comply with the obligation to establish internal reporting channels under Article 8(3).

3. When Member States adopt the provisions referred to in paragraphs 1 and 2, those provisions shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made. They shall forthwith communicate to the Commission the text of those provisions.

Article 27

Reporting, evaluation and review

1. Member States shall provide the Commission with all relevant information regarding the implementation and application of this Directive. On the basis of the information provided, the. Commission shall, by … [four years after the date of entry into force of this Directive], submit a report to the European Parliament and the Council on the implementation and application of this Directive.

2. Without prejudice to reporting obligations laid down in other Union legal acts, Member States shall, on an annual basis, submit the following statistics on the reports referred to in Chapter III to the Commission, preferably in an aggregated form, if they are available at a central level in the Member State concerned:

   (a) the number of reports received by the competent authorities;

   (b) the number of investigations and proceedings initiated as a result of such reports and their outcome; and

   (c) if ascertained, the estimated financial damage, and the amounts recovered following investigations and proceedings, related to the breaches reported.

3. The Commission shall, by … [six years after the date of entry into force of this Directive], taking into account its report submitted pursuant to paragraph 1 and the Member States' statistics submitted pursuant to paragraph 2, submit a report to the European Parliament and to the Council assessing the impact of national law transposing this Directive. The report shall evaluate the way in which this Directive has functioned and consider the need for additional measures, including, where appropriate, amendments with a view to extending the scope of this Directive to further Union acts or areas, in particular the improvement of the working environment to protect workers' health and safety and working conditions.

In addition to the evaluation referred to in the first subparagraph, the report shall evaluate how Member States made use of existing cooperation mechanisms as part of their obligations to follow up on reports regarding breaches falling within the scope of this Directive and more generally how they cooperate in cases of breaches with a cross-border dimension.

4. The Commission shall make the reports referred to in paragraphs 1 and 3 public and easily accessible.

Article 28

Entry into force

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

Article 29

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg,

For the European Parliament	*For the Council*
The President	*The President*

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);

(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, 10.06.2009, 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);

(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 CO_2 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 CO_2 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 CO_2 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 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 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);

(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).

Part II

Article 3(1) refers to the following Union legislation:

A. Point (a)(ii) of Article 2(1) – financial services, products and markets, and prevention of money laundering and terrorist financing:

1. Financial services:

(i) Directive 2009/65/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) (OJ L 302, 17.11.2009, p. 32);

(ii) Directive (EU) 2016/2341 of the European Parliament and of the Council of 14 December 2016 on the activities and supervision of institutions for occupational retirement provision (IORPs) (OJ L 354, 23.12.2016, p. 37);

(iii) Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC (OJ L 157, 9.6.2006, p. 87);

(iv) Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (market abuse regulation) and repealing Directive 2003/6/EC of the European Parliament and of the Council and Commission Directives 2003/124/EC, 2003/125/EC and 2004/72/EC (OJ L 173, 12.6.2014, p. 1);

(v) 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);

(vi) Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (OJ L 173, 12.6.2014, p. 349);

(vii) Regulation (EU) No 909/2014 of the European Parliament and of the Council of 23 July 2014 on improving securities settlement in the European Union and on central securities depositories and amending Directives 98/26/EC and 2014/65/EU and Regulation (EU) No 236/2012 (OJ L 257, 28.8.2014, p. 1);

(viii) Regulation (EU) No 1286/2014 of the European Parliament and of the Council of 26 November 2014 on key information documents for packaged retail and insurance-based investment products (PRIIPs) (OJ L 352, 9.12.2014, p. 1);

(ix) Regulation (EU) 2015/2365 of the European Parliament and of the Council of 25 November 2015 on transparency of securities financing transactions and of reuse and amending Regulation (EU) No 648/2012 (OJ L 337, 23.12.2015, p. 1);

(x) Directive (EU) 2016/97 of the European Parliament and of the Council of 20 January 2016 on insurance distribution (OJ L 26, 2.2.2016, p. 19);

(xi) Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC (OJ L 168, 30.6.2017, p. 12).

2. Prevention of money laundering and terrorist financing:

(i) Directive (EU) 2015/849 of the European Parliament and of the Council of 20 May 2015 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, amending Regulation (EU) No 648/2012 of the European Parliament and of the Council, and repealing Directive 2005/60/EC of the European Parliament and of the Council and Commission Directive 2006/70/EC (OJ L 141, 5.6.2015, p. 73);

(ii) Regulation (EU) 2015/847 of the European Parliament and of the Council of 20 May 2015 on information accompanying transfers of funds and repealing Regulation (EC) No 1781/2006 (OJ L 141, 5.6.2015, p. 1).

B. Point (a)(iv) of Article 2(1) – transport safety:

(i) Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (OJ L 122, 24.4.2014, p. 18);

(ii) Directive 2013/54/EU of the European Parliament and of the Council of 20 November 2013 concerning certain flag State responsibilities for compliance with and enforcement of the Maritime Labour Convention, 2006 (OJ L 329, 10.12.2013, p. 1);

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

C. Point (a)(v) of Article 2(1) – protection of the environment:

(i) Directive 2013/30/EU of the European Parliament and of the Council of 12 June 2013 on safety of offshore oil and gas operations and amending Directive 2004/35/EC (OJ L 178, 28.6.2013, p. 66).