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(*Legislative acts*)

REGULATIONS

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)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 16 thereof,

Having regard to the proposal from the European Commission,

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

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

Having regard to the opinion of the Committee of the Regions (²),

Acting in accordance with the ordinary legislative procedure (³),

Whereas:

- (1) The protection of natural persons in relation to the processing of personal data is a fundamental right. Article 8(1) of the Charter of Fundamental Rights of the European Union (the 'Charter') and Article 16(1) of the Treaty on the Functioning of the European Union (TFEU) provide that everyone has the right to the protection of personal data concerning him or her.
- (2) The principles of, and rules on the protection of natural persons with regard to the processing of their personal data should, whatever their nationality or residence, respect their fundamental rights and freedoms, in particular their right to the protection of personal data. This Regulation is intended to contribute to the accomplishment of an area of freedom, security and justice and of an economic union, to economic and social progress, to the strengthening and the convergence of the economies within the internal market, and to the well-being of natural persons.
- (3) Directive 95/46/EC of the European Parliament and of the Council (⁴) seeks to harmonise the protection of fundamental rights and freedoms of natural persons in respect of processing activities and to ensure the free flow of personal data between Member States.

(¹) OJ C 229, 31.7.2012, p. 90.

(²) OJ C 391, 18.12.2012, p. 127.

(³) Position of the European Parliament of 12 March 2014 (not yet published in the Official Journal) and position of the Council at first reading of 8 April 2016 (not yet published in the Official Journal). Position of the European Parliament of 14 April 2016.

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

- (4) The processing of personal data should be designed to serve mankind. The right to the protection of personal data is not an absolute right; it must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality. This Regulation respects all fundamental rights and observes the freedoms and principles recognised in the Charter as enshrined in the Treaties, in particular the respect for private and family life, home and communications, the protection of personal data, freedom of thought, conscience and religion, freedom of expression and information, freedom to conduct a business, the right to an effective remedy and to a fair trial, and cultural, religious and linguistic diversity.
- (5) The economic and social integration resulting from the functioning of the internal market has led to a substantial increase in cross-border flows of personal data. The exchange of personal data between public and private actors, including natural persons, associations and undertakings across the Union has increased. National authorities in the Member States are being called upon by Union law to cooperate and exchange personal data so as to be able to perform their duties or carry out tasks on behalf of an authority in another Member State.
- (6) Rapid technological developments and globalisation have brought new challenges for the protection of personal data. The scale of the collection and sharing of personal data has increased significantly. Technology allows both private companies and public authorities to make use of personal data on an unprecedented scale in order to pursue their activities. Natural persons increasingly make personal information available publicly and globally. Technology has transformed both the economy and social life, and should further facilitate the free flow of personal data within the Union and the transfer to third countries and international organisations, while ensuring a high level of the protection of personal data.
- (7) Those developments require a strong and more coherent data protection framework in the Union, backed by strong enforcement, given the importance of creating the trust that will allow the digital economy to develop across the internal market. Natural persons should have control of their own personal data. Legal and practical certainty for natural persons, economic operators and public authorities should be enhanced.
- (8) Where this Regulation provides for specifications or restrictions of its rules by Member State law, Member States may, as far as necessary for coherence and for making the national provisions comprehensible to the persons to whom they apply, incorporate elements of this Regulation into their national law.
- (9) The objectives and principles of Directive 95/46/EC remain sound, but it has not prevented fragmentation in the implementation of data protection across the Union, legal uncertainty or a widespread public perception that there are significant risks to the protection of natural persons, in particular with regard to online activity. Differences in the level of protection of the rights and freedoms of natural persons, in particular the right to the protection of personal data, with regard to the processing of personal data in the Member States may prevent the free flow of personal data throughout the Union. Those differences may therefore constitute an obstacle to the pursuit of economic activities at the level of the Union, distort competition and impede authorities in the discharge of their responsibilities under Union law. Such a difference in levels of protection is due to the existence of differences in the implementation and application of Directive 95/46/EC.
- (10) In order to ensure a consistent and high level of protection of natural persons and to remove the obstacles to flows of personal data within the Union, the level of protection of the rights and freedoms of natural persons with regard to the processing of such data should be equivalent in all Member States. Consistent and homogenous application of the rules for the protection of the fundamental rights and freedoms of natural persons with regard to the processing of personal data should be ensured throughout the Union. Regarding the processing of personal data for compliance with a legal obligation, for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, Member States should be allowed to maintain or introduce national provisions to further specify the application of the rules of this Regulation. In conjunction with the general and horizontal law on data protection implementing Directive 95/46/EC, Member States have several sector-specific laws in areas that need more specific provisions. This Regulation also provides a margin of manoeuvre for Member States to specify its rules, including for the processing of special categories of personal data ('sensitive data'). To that extent, this Regulation does not exclude Member State law that sets out the circumstances for specific processing situations, including determining more precisely the conditions under which the processing of personal data is lawful.

- (11) Effective protection of personal data throughout the Union requires the strengthening and setting out in detail of the rights of data subjects and the obligations of those who process and determine the processing of personal data, as well as equivalent powers for monitoring and ensuring compliance with the rules for the protection of personal data and equivalent sanctions for infringements in the Member States.
- (12) Article 16(2) TFEU mandates the European Parliament and the Council to lay down the rules relating to the protection of natural persons with regard to the processing of personal data and the rules relating to the free movement of personal data.
- (13) In order to ensure a consistent level of protection for natural persons throughout the Union and to prevent divergences hampering the free movement of personal data within the internal market, a Regulation is necessary to provide legal certainty and transparency for economic operators, including micro, small and medium-sized enterprises, and to provide natural persons in all Member States with the same level of legally enforceable rights and obligations and responsibilities for controllers and processors, to ensure consistent monitoring of the processing of personal data, and equivalent sanctions in all Member States as well as effective cooperation between the supervisory authorities of different Member States. The proper functioning of the internal market requires that the free movement of personal data within the Union is not restricted or prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data. To take account of the specific situation of micro, small and medium-sized enterprises, this Regulation includes a derogation for organisations with fewer than 250 employees with regard to record-keeping. In addition, the Union institutions and bodies, and Member States and their supervisory authorities, are encouraged to take account of the specific needs of micro, small and medium-sized enterprises in the application of this Regulation. The notion of micro, small and medium-sized enterprises should draw from Article 2 of the Annex to Commission Recommendation 2003/361/EC (¹).
- (14) The protection afforded by this Regulation should apply to natural persons, whatever their nationality or place of residence, in relation to the processing of their personal data. This Regulation does not cover the processing of personal data which concerns legal persons and in particular undertakings established as legal persons, including the name and the form of the legal person and the contact details of the legal person.
- (15) In order to prevent creating a serious risk of circumvention, the protection of natural persons should be technologically neutral and should not depend on the techniques used. The protection of natural persons should apply to the processing of personal data by automated means, as well as to manual processing, if the personal data are contained or are intended to be contained in a filing system. Files or sets of files, as well as their cover pages, which are not structured according to specific criteria should not fall within the scope of this Regulation.
- (16) This Regulation does not apply to issues of protection of fundamental rights and freedoms or the free flow of personal data related to activities which fall outside the scope of Union law, such as activities concerning national security. This Regulation does not apply to the processing of personal data by the Member States when carrying out activities in relation to the common foreign and security policy of the Union.
- (17) Regulation (EC) No 45/2001 of the European Parliament and of the Council (²) applies to the processing of personal data by the Union institutions, bodies, offices and agencies. Regulation (EC) No 45/2001 and other Union legal acts applicable to such processing of personal data should be adapted to the principles and rules established in this Regulation and applied in the light of this Regulation. In order to provide a strong and coherent data protection framework in the Union, the necessary adaptations of Regulation (EC) No 45/2001 should follow after the adoption of this Regulation, in order to allow application at the same time as this Regulation.
- (18) This Regulation does not apply to the processing of personal data by a natural person in the course of a purely personal or household activity and thus with no connection to a professional or commercial activity. Personal or

(¹) Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (C(2003) 1422) (OJ L 124, 20.5.2003, p. 36).

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

household activities could include correspondence and the holding of addresses, or social networking and online activity undertaken within the context of such activities. However, this Regulation applies to controllers or processors which provide the means for processing personal data for such personal or household activities.

- (19) 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, including the safeguarding against and the prevention of threats to public security and the free movement of such data, is the subject of a specific Union legal act. This Regulation should not, therefore, apply to processing activities for those purposes. However, personal data processed by public authorities under this Regulation should, when used for those purposes, be governed by a more specific Union legal act, namely Directive (EU) 2016/680 of the European Parliament and of the Council (¹). Member States may entrust competent authorities within the meaning of Directive (EU) 2016/680 with tasks which are not necessarily carried out for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and prevention of threats to public security, so that the processing of personal data for those other purposes, in so far as it is within the scope of Union law, falls within the scope of this Regulation.

With regard to the processing of personal data by those competent authorities for purposes falling within scope of this Regulation, Member States should be able to maintain or introduce more specific provisions to adapt the application of the rules of this Regulation. Such provisions may determine more precisely specific requirements for the processing of personal data by those competent authorities for those other purposes, taking into account the constitutional, organisational and administrative structure of the respective Member State. When the processing of personal data by private bodies falls within the scope of this Regulation, this Regulation should provide for the possibility for Member States under specific conditions to restrict by law certain obligations and rights when such a restriction constitutes a necessary and proportionate measure in a democratic society to safeguard specific important interests including public security and the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security. This is relevant for instance in the framework of anti-money laundering or the activities of forensic laboratories.

- (20) While this Regulation applies, inter alia, to the activities of courts and other judicial authorities, Union or Member State law could specify the processing operations and processing procedures in relation to the processing of personal data by courts and other judicial authorities. The competence of the supervisory authorities should not cover the processing of personal data when courts are acting in their judicial capacity, in order to safeguard the independence of the judiciary in the performance of its judicial tasks, including decision-making. It should be possible to entrust supervision of such data processing operations to specific bodies within the judicial system of the Member State, which should, in particular ensure compliance with the rules of this Regulation, enhance awareness among members of the judiciary of their obligations under this Regulation and handle complaints in relation to such data processing operations.
- (21) This Regulation is without prejudice to the application of Directive 2000/31/EC of the European Parliament and of the Council (²), in particular of the liability rules of intermediary service providers in Articles 12 to 15 of that Directive. That Directive seeks to contribute to the proper functioning of the internal market by ensuring the free movement of information society services between Member States.
- (22) Any processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union should be carried out in accordance with this Regulation, regardless of whether the processing itself takes place within the Union. Establishment implies the effective and real exercise of activity through stable arrangements. The legal form of such arrangements, whether through a branch or a subsidiary with a legal personality, is not the determining factor in that respect.

(¹) 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 prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and the free movement of such data and repealing Council Framework Decision 2008/977/JHA (see page 89 of this Official Journal).

(²) Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') (OJ L 178, 17.7.2000, p. 1).

- (23) In order to ensure that natural persons are not deprived of the protection to which they are entitled under this Regulation, the processing of personal data of data subjects who are in the Union by a controller or a processor not established in the Union should be subject to this Regulation where the processing activities are related to offering goods or services to such data subjects irrespective of whether connected to a payment. In order to determine whether such a controller or processor is offering goods or services to data subjects who are in the Union, it should be ascertained whether it is apparent that the controller or processor envisages offering services to data subjects in one or more Member States in the Union. Whereas the mere accessibility of the controller's, processor's or an intermediary's website in the Union, of an email address or of other contact details, or the use of a language generally used in the third country where the controller is established, is insufficient to ascertain such intention, factors such as the use of a language or a currency generally used in one or more Member States with the possibility of ordering goods and services in that other language, or the mentioning of customers or users who are in the Union, may make it apparent that the controller envisages offering goods or services to data subjects in the Union.
- (24) The processing of personal data of data subjects who are in the Union by a controller or processor not established in the Union should also be subject to this Regulation when it is related to the monitoring of the behaviour of such data subjects in so far as their behaviour takes place within the Union. In order to determine whether a processing activity can be considered to monitor the behaviour of data subjects, it should be ascertained whether natural persons are tracked on the internet including potential subsequent use of personal data processing techniques which consist of profiling a natural person, particularly in order to take decisions concerning her or him or for analysing or predicting her or his personal preferences, behaviours and attitudes.
- (25) Where Member State law applies by virtue of public international law, this Regulation should also apply to a controller not established in the Union, such as in a Member State's diplomatic mission or consular post.
- (26) The principles of data protection should apply to any information concerning an identified or identifiable natural person. Personal data which have undergone pseudonymisation, which could be attributed to a natural person by the use of additional information should be considered to be information on an identifiable natural person. To determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments. The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes.
- (27) This Regulation does not apply to the personal data of deceased persons. Member States may provide for rules regarding the processing of personal data of deceased persons.
- (28) The application of pseudonymisation to personal data can reduce the risks to the data subjects concerned and help controllers and processors to meet their data-protection obligations. The explicit introduction of 'pseudonymisation' in this Regulation is not intended to preclude any other measures of data protection.
- (29) In order to create incentives to apply pseudonymisation when processing personal data, measures of pseudonymisation should, whilst allowing general analysis, be possible within the same controller when that controller has taken technical and organisational measures necessary to ensure, for the processing concerned, that this Regulation is implemented, and that additional information for attributing the personal data to a specific data subject is kept separately. The controller processing the personal data should indicate the authorised persons within the same controller.

- (30) Natural persons may be associated with online identifiers provided by their devices, applications, tools and protocols, such as internet protocol addresses, cookie identifiers or other identifiers such as radio frequency identification tags. This may leave traces which, in particular when combined with unique identifiers and other information received by the servers, may be used to create profiles of the natural persons and identify them.
- (31) Public authorities to which personal data are disclosed in accordance with a legal obligation for the exercise of their official mission, such as tax and customs authorities, financial investigation units, independent administrative authorities, or financial market authorities responsible for the regulation and supervision of securities markets should not be regarded as recipients if they receive personal data which are necessary to carry out a particular inquiry in the general interest, in accordance with Union or Member State law. The requests for disclosure sent by the public authorities should always be in writing, reasoned and occasional and should not concern the entirety of a filing system or lead to the interconnection of filing systems. The processing of personal data by those public authorities should comply with the applicable data-protection rules according to the purposes of the processing.
- (32) Consent should be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement. This could include ticking a box when visiting an internet website, choosing technical settings for information society services or another statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of his or her personal data. Silence, pre-ticked boxes or inactivity should not therefore constitute consent. Consent should cover all processing activities carried out for the same purpose or purposes. When the processing has multiple purposes, consent should be given for all of them. If the data subject's consent is to be given following a request by electronic means, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided.
- (33) It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.
- (34) Genetic data should be defined as personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained.
- (35) Personal data concerning health should include all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services as referred to in Directive 2011/24/EU of the European Parliament and of the Council (¹) to that natural person; a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test.
- (36) The main establishment of a controller in the Union should be the place of its central administration in the Union, unless the decisions on the purposes and means of the processing of personal data are taken in another establishment of the controller in the Union, in which case that other establishment should be considered to be

(¹) 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).

the main establishment. The main establishment of a controller in the Union should be determined according to objective criteria and should imply the effective and real exercise of management activities determining the main decisions as to the purposes and means of processing through stable arrangements. That criterion should not depend on whether the processing of personal data is carried out at that location. The presence and use of technical means and technologies for processing personal data or processing activities do not, in themselves, constitute a main establishment and are therefore not determining criteria for a main establishment. The main establishment of the processor should be the place of its central administration in the Union or, if it has no central administration in the Union, the place where the main processing activities take place in the Union. In cases involving both the controller and the processor, the competent lead supervisory authority should remain the supervisory authority of the Member State where the controller has its main establishment, but the supervisory authority of the processor should be considered to be a supervisory authority concerned and that supervisory authority should participate in the cooperation procedure provided for by this Regulation. In any case, the supervisory authorities of the Member State or Member States where the processor has one or more establishments should not be considered to be supervisory authorities concerned where the draft decision concerns only the controller. Where the processing is carried out by a group of undertakings, the main establishment of the controlling undertaking should be considered to be the main establishment of the group of undertakings, except where the purposes and means of processing are determined by another undertaking.

- (37) A group of undertakings should cover a controlling undertaking and its controlled undertakings, whereby the controlling undertaking should be the undertaking which can exert a dominant influence over the other undertakings by virtue, for example, of ownership, financial participation or the rules which govern it or the power to have personal data protection rules implemented. An undertaking which controls the processing of personal data in undertakings affiliated to it should be regarded, together with those undertakings, as a group of undertakings.
- (38) Children merit specific protection with regard to their personal data, as they may be less aware of the risks, consequences and safeguards concerned and their rights in relation to the processing of personal data. Such specific protection should, in particular, apply to the use of personal data of children for the purposes of marketing or creating personality or user profiles and the collection of personal data with regard to children when using services offered directly to a child. The consent of the holder of parental responsibility should not be necessary in the context of preventive or counselling services offered directly to a child.
- (39) Any processing of personal data should be lawful and fair. It should be transparent to natural persons that personal data concerning them are collected, used, consulted or otherwise processed and to what extent the personal data are or will be processed. The principle of transparency requires that any information and communication relating to the processing of those personal data be easily accessible and easy to understand, and that clear and plain language be used. That principle concerns, in particular, information to the data subjects on the identity of the controller and the purposes of the processing and further information to ensure fair and transparent processing in respect of the natural persons concerned and their right to obtain confirmation and communication of personal data concerning them which are being processed. Natural persons should be made aware of risks, rules, safeguards and rights in relation to the processing of personal data and how to exercise their rights in relation to such processing. In particular, the specific purposes for which personal data are processed should be explicit and legitimate and determined at the time of the collection of the personal data. The personal data should be adequate, relevant and limited to what is necessary for the purposes for which they are processed. This requires, in particular, ensuring that the period for which the personal data are stored is limited to a strict minimum. Personal data should be processed only if the purpose of the processing could not reasonably be fulfilled by other means. In order to ensure that the personal data are not kept longer than necessary, time limits should be established by the controller for erasure or for a periodic review. Every reasonable step should be taken to ensure that personal data which are inaccurate are rectified or deleted. Personal data should be processed in a manner that ensures appropriate security and confidentiality of the personal data, including for preventing unauthorised access to or use of personal data and the equipment used for the processing.
- (40) In order for processing to be lawful, personal data should be processed on the basis of the consent of the data subject concerned or some other legitimate basis, laid down by law, either in this Regulation or in other Union or

Member State law as referred to in this Regulation, including the necessity for compliance with the legal obligation to which the controller is subject or the necessity for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract.

- (41) Where this Regulation refers to a legal basis or a legislative measure, this does not necessarily require a legislative act adopted by a parliament, without prejudice to requirements pursuant to the constitutional order of the Member State concerned. However, such a legal basis or legislative measure should be clear and precise and its application should be foreseeable to persons subject to it, in accordance with the case-law of the Court of Justice of the European Union (the 'Court of Justice') and the European Court of Human Rights.
- (42) Where processing is based on the data subject's consent, the controller should be able to demonstrate that the data subject has given consent to the processing operation. In particular in the context of a written declaration on another matter, safeguards should ensure that the data subject is aware of the fact that and the extent to which consent is given. In accordance with Council Directive 93/13/EEC⁽¹⁾ a declaration of consent pre-formulated by the controller should be provided in an intelligible and easily accessible form, using clear and plain language and it should not contain unfair terms. For consent to be informed, the data subject should be aware at least of the identity of the controller and the purposes of the processing for which the personal data are intended. Consent should not be regarded as freely given if the data subject has no genuine or free choice or is unable to refuse or withdraw consent without detriment.
- (43) In order to ensure that consent is freely given, consent should not provide a valid legal ground for the processing of personal data in a specific case where there is a clear imbalance between the data subject and the controller, in particular where the controller is a public authority and it is therefore unlikely that consent was freely given in all the circumstances of that specific situation. Consent is presumed not to be freely given if it does not allow separate consent to be given to different personal data processing operations despite it being appropriate in the individual case, or if the performance of a contract, including the provision of a service, is dependent on the consent despite such consent not being necessary for such performance.
- (44) Processing should be lawful where it is necessary in the context of a contract or the intention to enter into a contract.
- (45) Where processing is carried out in accordance with a legal obligation to which the controller is subject or where processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority, the processing should have a basis in Union or Member State law. This Regulation does not require a specific law for each individual processing. A law as a basis for several processing operations based on a legal obligation to which the controller is subject or where processing is necessary for the performance of a task carried out in the public interest or in the exercise of an official authority may be sufficient. It should also be for Union or Member State law to determine the purpose of processing. Furthermore, that law could specify the general conditions of this Regulation governing the lawfulness of personal data processing, establish specifications for determining the controller, the type of personal data which are subject to the processing, the data subjects concerned, the entities to which the personal data may be disclosed, the purpose limitations, the storage period and other measures to ensure lawful and fair processing. It should also be for Union or Member State law to determine whether the controller performing a task carried out in the public interest or in the exercise of official authority should be a public authority or another natural or legal person governed by public law, or, where it is in the public interest to do so, including for health purposes such as public health and social protection and the management of health care services, by private law, such as a professional association.
- (46) The processing of personal data should also be regarded to be lawful where it is necessary to protect an interest which is essential for the life of the data subject or that of another natural person. Processing of personal data

⁽¹⁾ Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts (OJ L 95, 21.4.1993, p. 29).

based on the vital interest of another natural person should in principle take place only where the processing cannot be manifestly based on another legal basis. Some types of processing may serve both important grounds of public interest and the vital interests of the data subject as for instance when processing is necessary for humanitarian purposes, including for monitoring epidemics and their spread or in situations of humanitarian emergencies, in particular in situations of natural and man-made disasters.

- (47) The legitimate interests of a controller, including those of a controller to which the personal data may be disclosed, or of a third party, may provide a legal basis for processing, provided that the interests or the fundamental rights and freedoms of the data subject are not overriding, taking into consideration the reasonable expectations of data subjects based on their relationship with the controller. Such legitimate interest could exist for example where there is a relevant and appropriate relationship between the data subject and the controller in situations such as where the data subject is a client or in the service of the controller. At any rate the existence of a legitimate interest would need careful assessment including whether a data subject can reasonably expect at the time and in the context of the collection of the personal data that processing for that purpose may take place. The interests and fundamental rights of the data subject could in particular override the interest of the data controller where personal data are processed in circumstances where data subjects do not reasonably expect further processing. Given that it is for the legislator to provide by law for the legal basis for public authorities to process personal data, that legal basis should not apply to the processing by public authorities in the performance of their tasks. The processing of personal data strictly necessary for the purposes of preventing fraud also constitutes a legitimate interest of the data controller concerned. The processing of personal data for direct marketing purposes may be regarded as carried out for a legitimate interest.
- (48) Controllers that are part of a group of undertakings or institutions affiliated to a central body may have a legitimate interest in transmitting personal data within the group of undertakings for internal administrative purposes, including the processing of clients' or employees' personal data. The general principles for the transfer of personal data, within a group of undertakings, to an undertaking located in a third country remain unaffected.
- (49) The processing of personal data to the extent strictly necessary and proportionate for the purposes of ensuring network and information security, i.e. the ability of a network or an information system to resist, at a given level of confidence, accidental events or unlawful or malicious actions that compromise the availability, authenticity, integrity and confidentiality of stored or transmitted personal data, and the security of the related services offered by, or accessible via, those networks and systems, by public authorities, by computer emergency response teams (CERTs), computer security incident response teams (CSIRTs), by providers of electronic communications networks and services and by providers of security technologies and services, constitutes a legitimate interest of the data controller concerned. This could, for example, include preventing unauthorised access to electronic communications networks and malicious code distribution and stopping 'denial of service' attacks and damage to computer and electronic communication systems.
- (50) The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected. In such a case, no legal basis separate from that which allowed the collection of the personal data is required. If the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, Union or Member State law may determine and specify the tasks and purposes for which the further processing should be regarded as compatible and lawful. Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be considered to be compatible lawful processing operations. The legal basis provided by Union or Member State law for the processing of personal data may also provide a legal basis for further processing. In order to ascertain whether a purpose of further processing is compatible with the purpose for which the personal data are initially collected, the controller, after having met all the requirements for the lawfulness of the original processing, should take into account, inter alia: any link between those purposes and the purposes of the intended further processing; the context in which the personal data have been collected, in particular the reasonable expectations of data subjects based on their relationship with the controller as to their

further use; the nature of the personal data; the consequences of the intended further processing for data subjects; and the existence of appropriate safeguards in both the original and intended further processing operations.

Where the data subject has given consent or the processing is based on Union or Member State law which constitutes a necessary and proportionate measure in a democratic society to safeguard, in particular, important objectives of general public interest, the controller should be allowed to further process the personal data irrespective of the compatibility of the purposes. In any case, the application of the principles set out in this Regulation and in particular the information of the data subject on those other purposes and on his or her rights including the right to object, should be ensured. Indicating possible criminal acts or threats to public security by the controller and transmitting the relevant personal data in individual cases or in several cases relating to the same criminal act or threats to public security to a competent authority should be regarded as being in the legitimate interest pursued by the controller. However, such transmission in the legitimate interest of the controller or further processing of personal data should be prohibited if the processing is not compatible with a legal, professional or other binding obligation of secrecy.

- (51) Personal data which are, by their nature, particularly sensitive in relation to fundamental rights and freedoms merit specific protection as the context of their processing could create significant risks to the fundamental rights and freedoms. Those personal data should include personal data revealing racial or ethnic origin, whereby the use of the term 'racial origin' in this Regulation does not imply an acceptance by the Union of theories which attempt to determine the existence of separate human races. The processing of photographs should not systematically be considered to be processing of special categories of personal data as they are covered by the definition of biometric data only when processed through a specific technical means allowing the unique identification or authentication of a natural person. Such personal data should not be processed, unless processing is allowed in specific cases set out in this Regulation, taking into account that Member States law may lay down specific provisions on data protection in order to adapt the application of the rules of this Regulation for compliance with a legal obligation or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. In addition to the specific requirements for such processing, the general principles and other rules of this Regulation should apply, in particular as regards the conditions for lawful processing. Derogations from the general prohibition for processing such special categories of personal data should be explicitly provided, *inter alia*, where the data subject gives his or her explicit consent or in respect of specific needs in particular where the processing is carried out in the course of legitimate activities by certain associations or foundations the purpose of which is to permit the exercise of fundamental freedoms.
- (52) Derogating from the prohibition on processing special categories of personal data should also be allowed when provided for in Union or Member State law and subject to suitable safeguards, so as to protect personal data and other fundamental rights, where it is in the public interest to do so, in particular processing personal data in the field of employment law, social protection law including pensions and for health security, monitoring and alert purposes, the prevention or control of communicable diseases and other serious threats to health. Such a derogation may be made for health purposes, including public health and the management of health-care services, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system, or for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. A derogation should also allow the processing of such personal data where necessary for the establishment, exercise or defence of legal claims, whether in court proceedings or in an administrative or out-of-court procedure.
- (53) Special categories of personal data which merit higher protection should be processed for health-related purposes only where necessary to achieve those purposes for the benefit of natural persons and society as a whole, in particular in the context of the management of health or social care services and systems, including processing by the management and central national health authorities of such data for the purpose of quality control, management information and the general national and local supervision of the health or social care system, and ensuring continuity of health or social care and cross-border healthcare or health security, monitoring and alert purposes, or for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, based on Union or Member State law which has to meet an objective of public interest, as well as for studies conducted in the public interest in the area of public health. Therefore, this Regulation should provide for harmonised conditions for the processing of special categories of personal data concerning health, in respect of specific needs, in particular where the processing of such data is carried out for certain health-related purposes

by persons subject to a legal obligation of professional secrecy. Union or Member State law should provide for specific and suitable measures so as to protect the fundamental rights and the personal data of natural persons. Member States should be allowed to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health. However, this should not hamper the free flow of personal data within the Union when those conditions apply to cross-border processing of such data.

- (54) The processing of special categories of personal data may be necessary for reasons of public interest in the areas of public health without consent of the data subject. Such processing should be subject to suitable and specific measures so as to protect the rights and freedoms of natural persons. In that context, 'public health' should be interpreted as defined in Regulation (EC) No 1338/2008 of the European Parliament and of the Council (1), namely all elements related to health, namely health status, including morbidity and disability, the determinants having an effect on that health status, health care needs, resources allocated to health care, the provision of, and universal access to, health care as well as health care expenditure and financing, and the causes of mortality. Such processing of data concerning health for reasons of public interest should not result in personal data being processed for other purposes by third parties such as employers or insurance and banking companies.
- (55) Moreover, the processing of personal data by official authorities for the purpose of achieving the aims, laid down by constitutional law or by international public law, of officially recognised religious associations, is carried out on grounds of public interest.
- (56) Where in the course of electoral activities, the operation of the democratic system in a Member State requires that political parties compile personal data on people's political opinions, the processing of such data may be permitted for reasons of public interest, provided that appropriate safeguards are established.
- (57) If the personal data processed by a controller do not permit the controller to identify a natural person, the data controller should not be obliged to acquire additional information in order to identify the data subject for the sole purpose of complying with any provision of this Regulation. However, the controller should not refuse to take additional information provided by the data subject in order to support the exercise of his or her rights. Identification should include the digital identification of a data subject, for example through authentication mechanism such as the same credentials, used by the data subject to log-in to the on-line service offered by the data controller.
- (58) The principle of transparency requires that any information addressed to the public or to the data subject be concise, easily accessible and easy to understand, and that clear and plain language and, additionally, where appropriate, visualisation be used. Such information could be provided in electronic form, for example, when addressed to the public, through a website. This is of particular relevance in situations where the proliferation of actors and the technological complexity of practice make it difficult for the data subject to know and understand whether, by whom and for what purpose personal data relating to him or her are being collected, such as in the case of online advertising. Given that children merit specific protection, any information and communication, where processing is addressed to a child, should be in such a clear and plain language that the child can easily understand.
- (59) Modalities should be provided for facilitating the exercise of the data subject's rights under this Regulation, including mechanisms to request and, if applicable, obtain, free of charge, in particular, access to and rectification or erasure of personal data and the exercise of the right to object. The controller should also provide means for requests to be made electronically, especially where personal data are processed by electronic means. The controller should be obliged to respond to requests from the data subject without undue delay and at the latest within one month and to give reasons where the controller does not intend to comply with any such requests.

(1) Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work (OJ L 354, 31.12.2008, p. 70).

- (60) The principles of fair and transparent processing require that the data subject be informed of the existence of the processing operation and its purposes. The controller should provide the data subject with any further information necessary to ensure fair and transparent processing taking into account the specific circumstances and context in which the personal data are processed. Furthermore, the data subject should be informed of the existence of profiling and the consequences of such profiling. Where the personal data are collected from the data subject, the data subject should also be informed whether he or she is obliged to provide the personal data and of the consequences, where he or she does not provide such data. That information may be provided in combination with standardised icons in order to give in an easily visible, intelligible and clearly legible manner, a meaningful overview of the intended processing. Where the icons are presented electronically, they should be machine-readable.
- (61) The information in relation to the processing of personal data relating to the data subject should be given to him or her at the time of collection from the data subject, or, where the personal data are obtained from another source, within a reasonable period, depending on the circumstances of the case. Where personal data can be legitimately disclosed to another recipient, the data subject should be informed when the personal data are first disclosed to the recipient. Where the controller intends to process the personal data for a purpose other than that for which they were collected, the controller should provide the data subject prior to that further processing with information on that other purpose and other necessary information. Where the origin of the personal data cannot be provided to the data subject because various sources have been used, general information should be provided.
- (62) However, it is not necessary to impose the obligation to provide information where the data subject already possesses the information, where the recording or disclosure of the personal data is expressly laid down by law or where the provision of information to the data subject proves to be impossible or would involve a disproportionate effort. The latter could in particular be the case where processing is carried out for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. In that regard, the number of data subjects, the age of the data and any appropriate safeguards adopted should be taken into consideration.
- (63) A data subject should have the right of access to personal data which have been collected concerning him or her, and to exercise that right easily and at reasonable intervals, in order to be aware of, and verify, the lawfulness of the processing. This includes the right for data subjects to have access to data concerning their health, for example the data in their medical records containing information such as diagnoses, examination results, assessments by treating physicians and any treatment or interventions provided. Every data subject should therefore have the right to know and obtain communication in particular with regard to the purposes for which the personal data are processed, where possible the period for which the personal data are processed, the recipients of the personal data, the logic involved in any automatic personal data processing and, at least when based on profiling, the consequences of such processing. Where possible, the controller should be able to provide remote access to a secure system which would provide the data subject with direct access to his or her personal data. That right should not adversely affect the rights or freedoms of others, including trade secrets or intellectual property and in particular the copyright protecting the software. However, the result of those considerations should not be a refusal to provide all information to the data subject. Where the controller processes a large quantity of information concerning the data subject, the controller should be able to request that, before the information is delivered, the data subject specify the information or processing activities to which the request relates.
- (64) The controller should use all reasonable measures to verify the identity of a data subject who requests access, in particular in the context of online services and online identifiers. A controller should not retain personal data for the sole purpose of being able to react to potential requests.
- (65) A data subject should have the right to have personal data concerning him or her rectified and a 'right to be forgotten' where the retention of such data infringes this Regulation or Union or Member State law to which the controller is subject. In particular, a data subject should have the right to have his or her personal data erased and no longer processed where the personal data are no longer necessary in relation to the purposes for which they are collected or otherwise processed, where a data subject has withdrawn his or her consent or objects to the processing of personal data concerning him or her, or where the processing of his or her personal data does not otherwise comply with this Regulation. That right is relevant in particular where the data subject has given

his or her consent as a child and is not fully aware of the risks involved by the processing, and later wants to remove such personal data, especially on the internet. The data subject should be able to exercise that right notwithstanding the fact that he or she is no longer a child. However, the further retention of the personal data should be lawful where it is necessary, for exercising the right of freedom of expression and information, for compliance with a legal obligation, for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, on the grounds of public interest in the area of public health, for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, or for the establishment, exercise or defence of legal claims.

- (66) To strengthen the right to be forgotten in the online environment, the right to erasure should also be extended in such a way that a controller who has made the personal data public should be obliged to inform the controllers which are processing such personal data to erase any links to, or copies or replications of those personal data. In doing so, that controller should take reasonable steps, taking into account available technology and the means available to the controller, including technical measures, to inform the controllers which are processing the personal data of the data subject's request.
- (67) Methods by which to restrict the processing of personal data could include, inter alia, temporarily moving the selected data to another processing system, making the selected personal data unavailable to users, or temporarily removing published data from a website. In automated filing systems, the restriction of processing should in principle be ensured by technical means in such a manner that the personal data are not subject to further processing operations and cannot be changed. The fact that the processing of personal data is restricted should be clearly indicated in the system.
- (68) To further strengthen the control over his or her own data, where the processing of personal data is carried out by automated means, the data subject should also be allowed to receive personal data concerning him or her which he or she has provided to a controller in a structured, commonly used, machine-readable and interoperable format, and to transmit it to another controller. Data controllers should be encouraged to develop interoperable formats that enable data portability. That right should apply where the data subject provided the personal data on the basis of his or her consent or the processing is necessary for the performance of a contract. It should not apply where processing is based on a legal ground other than consent or contract. By its very nature, that right should not be exercised against controllers processing personal data in the exercise of their public duties. It should therefore not apply where the processing of the personal data is necessary for compliance with a legal obligation to which the controller is subject or for the performance of a task carried out in the public interest or in the exercise of an official authority vested in the controller. The data subject's right to transmit or receive personal data concerning him or her should not create an obligation for the controllers to adopt or maintain processing systems which are technically compatible. Where, in a certain set of personal data, more than one data subject is concerned, the right to receive the personal data should be without prejudice to the rights and freedoms of other data subjects in accordance with this Regulation. Furthermore, that right should not prejudice the right of the data subject to obtain the erasure of personal data and the limitations of that right as set out in this Regulation and should, in particular, not imply the erasure of personal data concerning the data subject which have been provided by him or her for the performance of a contract to the extent that and for as long as the personal data are necessary for the performance of that contract. Where technically feasible, the data subject should have the right to have the personal data transmitted directly from one controller to another.
- (69) Where personal data might lawfully be processed because processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, or on grounds of the legitimate interests of a controller or a third party, a data subject should, nevertheless, be entitled to object to the processing of any personal data relating to his or her particular situation. It should be for the controller to demonstrate that its compelling legitimate interest overrides the interests or the fundamental rights and freedoms of the data subject.
- (70) Where personal data are processed for the purposes of direct marketing, the data subject should have the right to object to such processing, including profiling to the extent that it is related to such direct marketing, whether with regard to initial or further processing, at any time and free of charge. That right should be explicitly brought to the attention of the data subject and presented clearly and separately from any other information.

- (71) The data subject should have the right not to be subject to a decision, which may include a measure, evaluating personal aspects relating to him or her which is based solely on automated processing and which produces legal effects concerning him or her or similarly significantly affects him or her, such as automatic refusal of an online credit application or e-recruiting practices without any human intervention. Such processing includes 'profiling' that consists of any form of automated processing of personal data evaluating the personal aspects relating to a natural person, in particular to analyse or predict aspects concerning the data subject's performance at work, economic situation, health, personal preferences or interests, reliability or behaviour, location or movements, where it produces legal effects concerning him or her or similarly significantly affects him or her. However, decision-making based on such processing, including profiling, should be allowed where expressly authorised by Union or Member State law to which the controller is subject, including for fraud and tax-evasion monitoring and prevention purposes conducted in accordance with the regulations, standards and recommendations of Union institutions or national oversight bodies and to ensure the security and reliability of a service provided by the controller, or necessary for the entering or performance of a contract between the data subject and a controller, or when the data subject has given his or her explicit consent. In any case, such processing should be subject to suitable safeguards, which should include specific information to the data subject and the right to obtain human intervention, to express his or her point of view, to obtain an explanation of the decision reached after such assessment and to challenge the decision. Such measure should not concern a child.

In order to ensure fair and transparent processing in respect of the data subject, taking into account the specific circumstances and context in which the personal data are processed, the controller should use appropriate mathematical or statistical procedures for the profiling, implement technical and organisational measures appropriate to ensure, in particular, that factors which result in inaccuracies in personal data are corrected and the risk of errors is minimised, secure personal data in a manner that takes account of the potential risks involved for the interests and rights of the data subject and that prevents, inter alia, discriminatory effects on natural persons on the basis of racial or ethnic origin, political opinion, religion or beliefs, trade union membership, genetic or health status or sexual orientation, or that result in measures having such an effect. Automated decision-making and profiling based on special categories of personal data should be allowed only under specific conditions.

- (72) Profiling is subject to the rules of this Regulation governing the processing of personal data, such as the legal grounds for processing or data protection principles. The European Data Protection Board established by this Regulation (the 'Board') should be able to issue guidance in that context.
- (73) Restrictions concerning specific principles and the rights of information, access to and rectification or erasure of personal data, the right to data portability, the right to object, decisions based on profiling, as well as the communication of a personal data breach to a data subject and certain related obligations of the controllers may be imposed by Union or Member State law, as far as necessary and proportionate in a democratic society to safeguard public security, including the protection of human life especially in response to natural or manmade disasters, the prevention, investigation and prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security, or of breaches of ethics for regulated professions, other important objectives of general public interest of the Union or of a Member State, in particular an important economic or financial interest of the Union or of a Member State, the keeping of public registers kept for reasons of general public interest, further processing of archived personal data to provide specific information related to the political behaviour under former totalitarian state regimes or the protection of the data subject or the rights and freedoms of others, including social protection, public health and humanitarian purposes. Those restrictions should be in accordance with the requirements set out in the Charter and in the European Convention for the Protection of Human Rights and Fundamental Freedoms.
- (74) The responsibility and liability of the controller for any processing of personal data carried out by the controller or on the controller's behalf should be established. In particular, the controller should be obliged to implement appropriate and effective measures and be able to demonstrate the compliance of processing activities with this Regulation, including the effectiveness of the measures. Those measures should take into account the nature, scope, context and purposes of the processing and the risk to the rights and freedoms of natural persons.

- (75) The risk to the rights and freedoms of natural persons, of varying likelihood and severity, may result from personal data processing which could lead to physical, material or non-material damage, in particular: where the processing may give rise to discrimination, identity theft or fraud, financial loss, damage to the reputation, loss of confidentiality of personal data protected by professional secrecy, unauthorised reversal of pseudonymisation, or any other significant economic or social disadvantage; where data subjects might be deprived of their rights and freedoms or prevented from exercising control over their personal data; where personal data are processed which reveal racial or ethnic origin, political opinions, religion or philosophical beliefs, trade union membership, and the processing of genetic data, data concerning health or data concerning sex life or criminal convictions and offences or related security measures; where personal aspects are evaluated, in particular analysing or predicting aspects concerning performance at work, economic situation, health, personal preferences or interests, reliability or behaviour, location or movements, in order to create or use personal profiles; where personal data of vulnerable natural persons, in particular of children, are processed; or where processing involves a large amount of personal data and affects a large number of data subjects.
- (76) The likelihood and severity of the risk to the rights and freedoms of the data subject should be determined by reference to the nature, scope, context and purposes of the processing. Risk should be evaluated on the basis of an objective assessment, by which it is established whether data processing operations involve a risk or a high risk.
- (77) Guidance on the implementation of appropriate measures and on the demonstration of compliance by the controller or the processor, especially as regards the identification of the risk related to the processing, their assessment in terms of origin, nature, likelihood and severity, and the identification of best practices to mitigate the risk, could be provided in particular by means of approved codes of conduct, approved certifications, guidelines provided by the Board or indications provided by a data protection officer. The Board may also issue guidelines on processing operations that are considered to be unlikely to result in a high risk to the rights and freedoms of natural persons and indicate what measures may be sufficient in such cases to address such risk.
- (78) The protection of the rights and freedoms of natural persons with regard to the processing of personal data require that appropriate technical and organisational measures be taken to ensure that the requirements of this Regulation are met. In order to be able to demonstrate compliance with this Regulation, the controller should adopt internal policies and implement measures which meet in particular the principles of data protection by design and data protection by default. Such measures could consist, inter alia, of minimising the processing of personal data, pseudonymising personal data as soon as possible, transparency with regard to the functions and processing of personal data, enabling the data subject to monitor the data processing, enabling the controller to create and improve security features. When developing, designing, selecting and using applications, services and products that are based on the processing of personal data or process personal data to fulfil their task, producers of the products, services and applications should be encouraged to take into account the right to data protection when developing and designing such products, services and applications and, with due regard to the state of the art, to make sure that controllers and processors are able to fulfil their data protection obligations. The principles of data protection by design and by default should also be taken into consideration in the context of public tenders.
- (79) The protection of the rights and freedoms of data subjects as well as the responsibility and liability of controllers and processors, also in relation to the monitoring by and measures of supervisory authorities, requires a clear allocation of the responsibilities under this Regulation, including where a controller determines the purposes and means of the processing jointly with other controllers or where a processing operation is carried out on behalf of a controller.
- (80) Where a controller or a processor not established in the Union is processing personal data of data subjects who are in the Union whose processing activities are related to the offering of goods or services, irrespective of whether a payment of the data subject is required, to such data subjects in the Union, or to the monitoring of their behaviour as far as their behaviour takes place within the Union, the controller or the processor should designate a representative, unless the processing is occasional, does not include processing, on a large scale, of special categories of personal data or the processing of personal data relating to criminal convictions and offences, and is unlikely to result in a risk to the rights and freedoms of natural persons, taking into account the