

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)

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<sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions<sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure<sup>(3)</sup>,

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<sup>(4)</sup> 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.

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- (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

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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

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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<sup>(5)</sup>.

- (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<sup>(6)</sup> 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 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,

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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<sup>(7)</sup>. 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<sup>(8)</sup>, 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

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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.

- (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

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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

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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<sup>(9)</sup> 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 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



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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

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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<sup>(10)</sup> 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

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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 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

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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

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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

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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<sup>(11)</sup>, 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.

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- (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.
- (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

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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



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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

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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

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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.

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- (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

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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 nature, context, scope and purposes of the processing or if the controller is a public authority or body. The representative should act on behalf of the controller or the processor and may be addressed by any supervisory authority. The representative should be explicitly designated by a written mandate of the controller or of the processor to act on its behalf with regard to its obligations under this Regulation. The designation of such a representative does not affect the responsibility or liability of the controller or of the processor under this Regulation. Such a representative should perform its tasks according to the mandate received from the controller or processor, including cooperating with the competent supervisory authorities with regard to any action taken to ensure compliance with this Regulation. The designated representative should be subject to enforcement proceedings in the event of non-compliance by the controller or processor.
- (81) To ensure compliance with the requirements of this Regulation in respect of the processing to be carried out by the processor on behalf of the controller, when entrusting a processor with processing activities, the controller should use only processors providing sufficient guarantees, in particular in terms of expert knowledge, reliability and resources, to implement technical and organisational measures which will meet the requirements of this Regulation, including for the security of processing. The adherence of the processor to an approved code of conduct or an approved certification mechanism may be used as an element to demonstrate compliance with the obligations of the controller. The carrying-out of processing by a processor should be governed by a contract or other legal act under Union or Member State law, binding the processor to the controller, setting out the subject-matter and duration of the processing, the nature and purposes of the processing, the type of personal data and categories of data subjects, taking into account the specific tasks and responsibilities of the processor in

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the context of the processing to be carried out and the risk to the rights and freedoms of the data subject. The controller and processor may choose to use an individual contract or standard contractual clauses which are adopted either directly by the Commission or by a supervisory authority in accordance with the consistency mechanism and then adopted by the Commission. After the completion of the processing on behalf of the controller, the processor should, at the choice of the controller, return or delete the personal data, unless there is a requirement to store the personal data under Union or Member State law to which the processor is subject.

- (82) In order to demonstrate compliance with this Regulation, the controller or processor should maintain records of processing activities under its responsibility. Each controller and processor should be obliged to cooperate with the supervisory authority and make those records, on request, available to it, so that it might serve for monitoring those processing operations.
- (83) In order to maintain security and to prevent processing in infringement of this Regulation, the controller or processor should evaluate the risks inherent in the processing and implement measures to mitigate those risks, such as encryption. Those measures should ensure an appropriate level of security, including confidentiality, taking into account the state of the art and the costs of implementation in relation to the risks and the nature of the personal data to be protected. In assessing data security risk, consideration should be given to the risks that are presented by personal data processing, such as accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed which may in particular lead to physical, material or non-material damage.
- (84) In order to enhance compliance with this Regulation where processing operations are likely to result in a high risk to the rights and freedoms of natural persons, the controller should be responsible for the carrying-out of a data protection impact assessment to evaluate, in particular, the origin, nature, particularity and severity of that risk. The outcome of the assessment should be taken into account when determining the appropriate measures to be taken in order to demonstrate that the processing of personal data complies with this Regulation. Where a data-protection impact assessment indicates that processing operations involve a high risk which the controller cannot mitigate by appropriate measures in terms of available technology and costs of implementation, a consultation of the supervisory authority should take place prior to the processing.
- (85) A personal data breach may, if not addressed in an appropriate and timely manner, result in physical, material or non-material damage to natural persons such as loss of control over their personal data or limitation of their rights, discrimination, identity theft or fraud, financial loss, unauthorised reversal of pseudonymisation, damage to reputation, loss of confidentiality of personal data protected by professional secrecy or any other significant economic or social disadvantage to the natural person concerned. Therefore, as soon as the controller becomes aware that a personal data breach has occurred, the controller should notify the personal data breach to the supervisory authority without undue delay and, where feasible, not later than 72 hours after having become aware of

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it, unless the controller is able to demonstrate, in accordance with the accountability principle, that the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. Where such notification cannot be achieved within 72 hours, the reasons for the delay should accompany the notification and information may be provided in phases without undue further delay.

- (86) The controller should communicate to the data subject a personal data breach, without undue delay, where that personal data breach is likely to result in a high risk to the rights and freedoms of the natural person in order to allow him or her to take the necessary precautions. The communication should describe the nature of the personal data breach as well as recommendations for the natural person concerned to mitigate potential adverse effects. Such communications to data subjects should be made as soon as reasonably feasible and in close cooperation with the supervisory authority, respecting guidance provided by it or by other relevant authorities such as law-enforcement authorities. For example, the need to mitigate an immediate risk of damage would call for prompt communication with data subjects whereas the need to implement appropriate measures against continuing or similar personal data breaches may justify more time for communication.
- (87) It should be ascertained whether all appropriate technological protection and organisational measures have been implemented to establish immediately whether a personal data breach has taken place and to inform promptly the supervisory authority and the data subject. The fact that the notification was made without undue delay should be established taking into account in particular the nature and gravity of the personal data breach and its consequences and adverse effects for the data subject. Such notification may result in an intervention of the supervisory authority in accordance with its tasks and powers laid down in this Regulation.
- (88) In setting detailed rules concerning the format and procedures applicable to the notification of personal data breaches, due consideration should be given to the circumstances of that breach, including whether or not personal data had been protected by appropriate technical protection measures, effectively limiting the likelihood of identity fraud or other forms of misuse. Moreover, such rules and procedures should take into account the legitimate interests of law-enforcement authorities where early disclosure could unnecessarily hamper the investigation of the circumstances of a personal data breach.
- (89) Directive 95/46/EC provided for a general obligation to notify the processing of personal data to the supervisory authorities. While that obligation produces administrative and financial burdens, it did not in all cases contribute to improving the protection of personal data. Such indiscriminate general notification obligations should therefore be abolished, and replaced by effective procedures and mechanisms which focus instead on those types of processing operations which are likely to result in a high risk to the rights and freedoms of natural persons by virtue of their nature, scope, context and purposes. Such types of processing operations may be those which in, particular, involve using new technologies, or are of a new kind and where no data protection

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impact assessment has been carried out before by the controller, or where they become necessary in the light of the time that has elapsed since the initial processing.

- (90) In such cases, a data protection impact assessment should be carried out by the controller prior to the processing in order to assess the particular likelihood and severity of the high risk, taking into account the nature, scope, context and purposes of the processing and the sources of the risk. That impact assessment should include, in particular, the measures, safeguards and mechanisms envisaged for mitigating that risk, ensuring the protection of personal data and demonstrating compliance with this Regulation.
- (91) This should in particular apply to large-scale processing operations which aim to process a considerable amount of personal data at regional, national or supranational level and which could affect a large number of data subjects and which are likely to result in a high risk, for example, on account of their sensitivity, where in accordance with the achieved state of technological knowledge a new technology is used on a large scale as well as to other processing operations which result in a high risk to the rights and freedoms of data subjects, in particular where those operations render it more difficult for data subjects to exercise their rights. A data protection impact assessment should also be made where personal data are processed for taking decisions regarding specific natural persons following any systematic and extensive evaluation of personal aspects relating to natural persons based on profiling those data or following the processing of special categories of personal data, biometric data, or data on criminal convictions and offences or related security measures. A data protection impact assessment is equally required for monitoring publicly accessible areas on a large scale, especially when using optic-electronic devices or for any other operations where the competent supervisory authority considers that the processing is likely to result in a high risk to the rights and freedoms of data subjects, in particular because they prevent data subjects from exercising a right or using a service or a contract, or because they are carried out systematically on a large scale. The processing of personal data should not be considered to be on a large scale if the processing concerns personal data from patients or clients by an individual physician, other health care professional or lawyer. In such cases, a data protection impact assessment should not be mandatory.
- (92) There are circumstances under which it may be reasonable and economical for the subject of a data protection impact assessment to be broader than a single project, for example where public authorities or bodies intend to establish a common application or processing platform or where several controllers plan to introduce a common application or processing environment across an industry sector or segment or for a widely used horizontal activity.
- (93) In the context of the adoption of the Member State law on which the performance of the tasks of the public authority or public body is based and which regulates the specific processing operation or set of operations in question, Member States may deem it necessary to carry out such assessment prior to the processing activities.
- (94) Where a data protection impact assessment indicates that the processing would, in the absence of safeguards, security measures and mechanisms to mitigate the risk, result in a high risk to the rights and freedoms of natural persons and the controller is of the



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opinion that the risk cannot be mitigated by reasonable means in terms of available technologies and costs of implementation, the supervisory authority should be consulted prior to the start of processing activities. Such high risk is likely to result from certain types of processing and the extent and frequency of processing, which may result also in a realisation of damage or interference with the rights and freedoms of the natural person. The supervisory authority should respond to the request for consultation within a specified period. However, the absence of a reaction of the supervisory authority within that period should be without prejudice to any intervention of the supervisory authority in accordance with its tasks and powers laid down in this Regulation, including the power to prohibit processing operations. As part of that consultation process, the outcome of a data protection impact assessment carried out with regard to the processing at issue may be submitted to the supervisory authority, in particular the measures envisaged to mitigate the risk to the rights and freedoms of natural persons.

- (95) The processor should assist the controller, where necessary and upon request, in ensuring compliance with the obligations deriving from the carrying out of data protection impact assessments and from prior consultation of the supervisory authority.
- (96) A consultation of the supervisory authority should also take place in the course of the preparation of a legislative or regulatory measure which provides for the processing of personal data, in order to ensure compliance of the intended processing with this Regulation and in particular to mitigate the risk involved for the data subject.
- (97) Where the processing is carried out by a public authority, except for courts or independent judicial authorities when acting in their judicial capacity, where, in the private sector, processing is carried out by a controller whose core activities consist of processing operations that require regular and systematic monitoring of the data subjects on a large scale, or where the core activities of the controller or the processor consist of processing on a large scale of special categories of personal data and data relating to criminal convictions and offences, a person with expert knowledge of data protection law and practices should assist the controller or processor to monitor internal compliance with this Regulation. In the private sector, the core activities of a controller relate to its primary activities and do not relate to the processing of personal data as ancillary activities. The necessary level of expert knowledge should be determined in particular according to the data processing operations carried out and the protection required for the personal data processed by the controller or the processor. Such data protection officers, whether or not they are an employee of the controller, should be in a position to perform their duties and tasks in an independent manner.
- (98) Associations or other bodies representing categories of controllers or processors should be encouraged to draw up codes of conduct, within the limits of this Regulation, so as to facilitate the effective application of this Regulation, taking account of the specific characteristics of the processing carried out in certain sectors and the specific needs of micro, small and medium enterprises. In particular, such codes of conduct could calibrate the obligations of controllers and processors, taking into account the risk likely to result from the processing for the rights and freedoms of natural persons.

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- (99) When drawing up a code of conduct, or when amending or extending such a code, associations and other bodies representing categories of controllers or processors should consult relevant stakeholders, including data subjects where feasible, and have regard to submissions received and views expressed in response to such consultations.
- (100) In order to enhance transparency and compliance with this Regulation, the establishment of certification mechanisms and data protection seals and marks should be encouraged, allowing data subjects to quickly assess the level of data protection of relevant products and services.
- (101) Flows of personal data to and from countries outside the Union and international organisations are necessary for the expansion of international trade and international cooperation. The increase in such flows has raised new challenges and concerns with regard to the protection of personal data. However, when personal data are transferred from the Union to controllers, processors or other recipients in third countries or to international organisations, the level of protection of natural persons ensured in the Union by this Regulation should not be undermined, including in cases of onward transfers of personal data from the third country or international organisation to controllers, processors in the same or another third country or international organisation. In any event, transfers to third countries and international organisations may only be carried out in full compliance with this Regulation. A transfer could take place only if, subject to the other provisions of this Regulation, the conditions laid down in the provisions of this Regulation relating to the transfer of personal data to third countries or international organisations are complied with by the controller or processor.
- (102) This Regulation is without prejudice to international agreements concluded between the Union and third countries regulating the transfer of personal data including appropriate safeguards for the data subjects. Member States may conclude international agreements which involve the transfer of personal data to third countries or international organisations, as far as such agreements do not affect this Regulation or any other provisions of Union law and include an appropriate level of protection for the fundamental rights of the data subjects.
- (103) The Commission may decide with effect for the entire Union that a third country, a territory or specified sector within a third country, or an international organisation, offers an adequate level of data protection, thus providing legal certainty and uniformity throughout the Union as regards the third country or international organisation which is considered to provide such level of protection. In such cases, transfers of personal data to that third country or international organisation may take place without the need to obtain any further authorisation. The Commission may also decide, having given notice and a full statement setting out the reasons to the third country or international organisation, to revoke such a decision.
- (104) In line with the fundamental values on which the Union is founded, in particular the protection of human rights, the Commission should, in its assessment of the third country, or of a territory or specified sector within a third country, take into account how a particular third country respects the rule of law, access to justice as well as international human rights norms and standards and its general and sectoral

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law, including legislation concerning public security, defence and national security as well as public order and criminal law. The adoption of an adequacy decision with regard to a territory or a specified sector in a third country should take into account clear and objective criteria, such as specific processing activities and the scope of applicable legal standards and legislation in force in the third country. The third country should offer guarantees ensuring an adequate level of protection essentially equivalent to that ensured within the Union, in particular where personal data are processed in one or several specific sectors. In particular, the third country should ensure effective independent data protection supervision and should provide for cooperation mechanisms with the Member States' data protection authorities, and the data subjects should be provided with effective and enforceable rights and effective administrative and judicial redress.

- (105) Apart from the international commitments the third country or international organisation has entered into, the Commission should take account of obligations arising from the third country's or international organisation's participation in multilateral or regional systems in particular in relation to the protection of personal data, as well as the implementation of such obligations. In particular, the third country's accession to the Council of Europe Convention of 28 January 1981 for the Protection of Individuals with regard to the Automatic Processing of Personal Data and its Additional Protocol should be taken into account. The Commission should consult the Board when assessing the level of protection in third countries or international organisations.
- (106) The Commission should monitor the functioning of decisions on the level of protection in a third country, a territory or specified sector within a third country, or an international organisation, and monitor the functioning of decisions adopted on the basis of Article 25(6) or Article 26(4) of Directive 95/46/EC. In its adequacy decisions, the Commission should provide for a periodic review mechanism of their functioning. That periodic review should be conducted in consultation with the third country or international organisation in question and take into account all relevant developments in the third country or international organisation. For the purposes of monitoring and of carrying out the periodic reviews, the Commission should take into consideration the views and findings of the European Parliament and of the Council as well as of other relevant bodies and sources. The Commission should evaluate, within a reasonable time, the functioning of the latter decisions and report any relevant findings to the Committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>(12)</sup> as established under this Regulation, to the European Parliament and to the Council.
- (107) The Commission may recognise that a third country, a territory or a specified sector within a third country, or an international organisation no longer ensures an adequate level of data protection. Consequently the transfer of personal data to that third country or international organisation should be prohibited, unless the requirements in this Regulation relating to transfers subject to appropriate safeguards, including binding corporate rules, and derogations for specific situations are fulfilled. In that case, provision should be made for consultations between the Commission and such third countries or international organisations. The Commission should, in a timely manner,

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inform the third country or international organisation of the reasons and enter into consultations with it in order to remedy the situation.

- (108) In the absence of an adequacy decision, the controller or processor should take measures to compensate for the lack of data protection in a third country by way of appropriate safeguards for the data subject. Such appropriate safeguards may consist of making use of binding corporate rules, standard data protection clauses adopted by the Commission, standard data protection clauses adopted by a supervisory authority or contractual clauses authorised by a supervisory authority. Those safeguards should ensure compliance with data protection requirements and the rights of the data subjects appropriate to processing within the Union, including the availability of enforceable data subject rights and of effective legal remedies, including to obtain effective administrative or judicial redress and to claim compensation, in the Union or in a third country. They should relate in particular to compliance with the general principles relating to personal data processing, the principles of data protection by design and by default. Transfers may also be carried out by public authorities or bodies with public authorities or bodies in third countries or with international organisations with corresponding duties or functions, including on the basis of provisions to be inserted into administrative arrangements, such as a memorandum of understanding, providing for enforceable and effective rights for data subjects. Authorisation by the competent supervisory authority should be obtained when the safeguards are provided for in administrative arrangements that are not legally binding.
- (109) The possibility for the controller or processor to use standard data-protection clauses adopted by the Commission or by a supervisory authority should prevent controllers or processors neither from including the standard data-protection clauses in a wider contract, such as a contract between the processor and another processor, nor from adding other clauses or additional safeguards provided that they do not contradict, directly or indirectly, the standard contractual clauses adopted by the Commission or by a supervisory authority or prejudice the fundamental rights or freedoms of the data subjects. Controllers and processors should be encouraged to provide additional safeguards via contractual commitments that supplement standard protection clauses.
- (110) A group of undertakings, or a group of enterprises engaged in a joint economic activity, should be able to make use of approved binding corporate rules for its international transfers from the Union to organisations within the same group of undertakings, or group of enterprises engaged in a joint economic activity, provided that such corporate rules include all essential principles and enforceable rights to ensure appropriate safeguards for transfers or categories of transfers of personal data.
- (111) Provisions should be made for the possibility for transfers in certain circumstances where the data subject has given his or her explicit consent, where the transfer is occasional and necessary in relation to a contract or a legal claim, regardless of whether in a judicial procedure or whether in an administrative or any out-of-court procedure, including procedures before regulatory bodies. Provision should also be made for the possibility for transfers where important grounds of public interest laid down by Union or Member State law so require or where the transfer is made from a register established

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by law and intended for consultation by the public or persons having a legitimate interest. In the latter case, such a transfer should not involve the entirety of the personal data or entire categories of the data contained in the register and, when the register is intended for consultation by persons having a legitimate interest, the transfer should be made only at the request of those persons or, if they are to be the recipients, taking into full account the interests and fundamental rights of the data subject.

- (112) Those derogations should in particular apply to data transfers required and necessary for important reasons of public interest, for example in cases of international data exchange between competition authorities, tax or customs administrations, between financial supervisory authorities, between services competent for social security matters, or for public health, for example in the case of contact tracing for contagious diseases or in order to reduce and/or eliminate doping in sport. A transfer of personal data should also be regarded as lawful where it is necessary to protect an interest which is essential for the data subject's or another person's vital interests, including physical integrity or life, if the data subject is incapable of giving consent. In the absence of an adequacy decision, Union or Member State law may, for important reasons of public interest, expressly set limits to the transfer of specific categories of data to a third country or an international organisation. Member States should notify such provisions to the Commission. Any transfer to an international humanitarian organisation of personal data of a data subject who is physically or legally incapable of giving consent, with a view to accomplishing a task incumbent under the Geneva Conventions or to complying with international humanitarian law applicable in armed conflicts, could be considered to be necessary for an important reason of public interest or because it is in the vital interest of the data subject.
- (113) Transfers which can be qualified as not repetitive and that only concern a limited number of data subjects, could also be possible for the purposes of the compelling legitimate interests pursued by the controller, when those interests are not overridden by the interests or rights and freedoms of the data subject and when the controller has assessed all the circumstances surrounding the data transfer. The controller should give particular consideration to the nature of the personal data, the purpose and duration of the proposed processing operation or operations, as well as the situation in the country of origin, the third country and the country of final destination, and should provide suitable safeguards to protect fundamental rights and freedoms of natural persons with regard to the processing of their personal data. Such transfers should be possible only in residual cases where none of the other grounds for transfer are applicable. For scientific or historical research purposes or statistical purposes, the legitimate expectations of society for an increase of knowledge should be taken into consideration. The controller should inform the supervisory authority and the data subject about the transfer.
- (114) In any case, where the Commission has taken no decision on the adequate level of data protection in a third country, the controller or processor should make use of solutions that provide data subjects with enforceable and effective rights as regards the processing of their data in the Union once those data have been transferred so that they will continue to benefit from fundamental rights and safeguards.

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- (115) Some third countries adopt laws, regulations and other legal acts which purport to directly regulate the processing activities of natural and legal persons under the jurisdiction of the Member States. This may include judgments of courts or tribunals or decisions of administrative authorities in third countries requiring a controller or processor to transfer or disclose personal data, and which are not based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or a Member State. The extraterritorial application of those laws, regulations and other legal acts may be in breach of international law and may impede the attainment of the protection of natural persons ensured in the Union by this Regulation. Transfers should only be allowed where the conditions of this Regulation for a transfer to third countries are met. This may be the case, inter alia, where disclosure is necessary for an important ground of public interest recognised in Union or Member State law to which the controller is subject.
- (116) When personal data moves across borders outside the Union it may put at increased risk the ability of natural persons to exercise data protection rights in particular to protect themselves from the unlawful use or disclosure of that information. At the same time, supervisory authorities may find that they are unable to pursue complaints or conduct investigations relating to the activities outside their borders. Their efforts to work together in the cross-border context may also be hampered by insufficient preventative or remedial powers, inconsistent legal regimes, and practical obstacles like resource constraints. Therefore, there is a need to promote closer cooperation among data protection supervisory authorities to help them exchange information and carry out investigations with their international counterparts. For the purposes of developing international cooperation mechanisms to facilitate and provide international mutual assistance for the enforcement of legislation for the protection of personal data, the Commission and the supervisory authorities should exchange information and cooperate in activities related to the exercise of their powers with competent authorities in third countries, based on reciprocity and in accordance with this Regulation.
- (117) The establishment of supervisory authorities in Member States, empowered to perform their tasks and exercise their powers with complete independence, is an essential component of the protection of natural persons with regard to the processing of their personal data. Member States should be able to establish more than one supervisory authority, to reflect their constitutional, organisational and administrative structure.
- (118) The independence of supervisory authorities should not mean that the supervisory authorities cannot be subject to control or monitoring mechanisms regarding their financial expenditure or to judicial review.
- (119) Where a Member State establishes several supervisory authorities, it should establish by law mechanisms for ensuring the effective participation of those supervisory authorities in the consistency mechanism. That Member State should in particular designate the supervisory authority which functions as a single contact point for the effective participation of those authorities in the mechanism, to ensure swift and smooth cooperation with other supervisory authorities, the Board and the Commission.

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- (120) Each supervisory authority should be provided with the financial and human resources, premises and infrastructure necessary for the effective performance of their tasks, including those related to mutual assistance and cooperation with other supervisory authorities throughout the Union. Each supervisory authority should have a separate, public annual budget, which may be part of the overall state or national budget.
- (121) The general conditions for the member or members of the supervisory authority should be laid down by law in each Member State and should in particular provide that those members are to be appointed, by means of a transparent procedure, either by the parliament, government or the head of State of the Member State on the basis of a proposal from the government, a member of the government, the parliament or a chamber of the parliament, or by an independent body entrusted under Member State law. In order to ensure the independence of the supervisory authority, the member or members should act with integrity, refrain from any action that is incompatible with their duties and should not, during their term of office, engage in any incompatible occupation, whether gainful or not. The supervisory authority should have its own staff, chosen by the supervisory authority or an independent body established by Member State law, which should be subject to the exclusive direction of the member or members of the supervisory authority.
- (122) Each supervisory authority should be competent on the territory of its own Member State to exercise the powers and to perform the tasks conferred on it in accordance with this Regulation. This should cover in particular the processing in the context of the activities of an establishment of the controller or processor on the territory of its own Member State, the processing of personal data carried out by public authorities or private bodies acting in the public interest, processing affecting data subjects on its territory or processing carried out by a controller or processor not established in the Union when targeting data subjects residing on its territory. This should include handling complaints lodged by a data subject, conducting investigations on the application of this Regulation and promoting public awareness of the risks, rules, safeguards and rights in relation to the processing of personal data.
- (123) The supervisory authorities should monitor the application of the provisions pursuant to this Regulation and contribute to its consistent application throughout the Union, in order to protect natural persons in relation to the processing of their personal data and to facilitate the free flow of personal data within the internal market. For that purpose, the supervisory authorities should cooperate with each other and with the Commission, without the need for any agreement between Member States on the provision of mutual assistance or on such cooperation.
- (124) Where the processing of personal data takes place in the context of the activities of an establishment of a controller or a processor in the Union and the controller or processor is established in more than one Member State, or where processing taking place in the context of the activities of a single establishment of a controller or processor in the Union substantially affects or is likely to substantially affect data subjects in more than one Member State, the supervisory authority for the main establishment of the controller or processor or for the single establishment of the controller or processor should act

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as lead authority. It should cooperate with the other authorities concerned, because the controller or processor has an establishment on the territory of their Member State, because data subjects residing on their territory are substantially affected, or because a complaint has been lodged with them. Also where a data subject not residing in that Member State has lodged a complaint, the supervisory authority with which such complaint has been lodged should also be a supervisory authority concerned. Within its tasks to issue guidelines on any question covering the application of this Regulation, the Board should be able to issue guidelines in particular on the criteria to be taken into account in order to ascertain whether the processing in question substantially affects data subjects in more than one Member State and on what constitutes a relevant and reasoned objection.

- (125) The lead authority should be competent to adopt binding decisions regarding measures applying the powers conferred on it in accordance with this Regulation. In its capacity as lead authority, the supervisory authority should closely involve and coordinate the supervisory authorities concerned in the decision-making process. Where the decision is to reject the complaint by the data subject in whole or in part, that decision should be adopted by the supervisory authority with which the complaint has been lodged.
- (126) The decision should be agreed jointly by the lead supervisory authority and the supervisory authorities concerned and should be directed towards the main or single establishment of the controller or processor and be binding on the controller and processor. The controller or processor should take the necessary measures to ensure compliance with this Regulation and the implementation of the decision notified by the lead supervisory authority to the main establishment of the controller or processor as regards the processing activities in the Union.
- (127) Each supervisory authority not acting as the lead supervisory authority should be competent to handle local cases where the controller or processor is established in more than one Member State, but the subject matter of the specific processing concerns only processing carried out in a single Member State and involves only data subjects in that single Member State, for example, where the subject matter concerns the processing of employees' personal data in the specific employment context of a Member State. In such cases, the supervisory authority should inform the lead supervisory authority without delay about the matter. After being informed, the lead supervisory authority should decide, whether it will handle the case pursuant to the provision on cooperation between the lead supervisory authority and other supervisory authorities concerned ('one-stop-shop mechanism'), or whether the supervisory authority which informed it should handle the case at local level. When deciding whether it will handle the case, the lead supervisory authority should take into account whether there is an establishment of the controller or processor in the Member State of the supervisory authority which informed it in order to ensure effective enforcement of a decision *vis-à-vis* the controller or processor. Where the lead supervisory authority decides to handle the case, the supervisory authority which informed it should have the possibility to submit a draft for a decision, of which the lead supervisory authority should take utmost account when preparing its draft decision in that one-stop-shop mechanism.



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- (128) The rules on the lead supervisory authority and the one-stop-shop mechanism should not apply where the processing is carried out by public authorities or private bodies in the public interest. In such cases the only supervisory authority competent to exercise the powers conferred to it in accordance with this Regulation should be the supervisory authority of the Member State where the public authority or private body is established.
- (129) In order to ensure consistent monitoring and enforcement of this Regulation throughout the Union, the supervisory authorities should have in each Member State the same tasks and effective powers, including powers of investigation, corrective powers and sanctions, and authorisation and advisory powers, in particular in cases of complaints from natural persons, and without prejudice to the powers of prosecutorial authorities under Member State law, to bring infringements of this Regulation to the attention of the judicial authorities and engage in legal proceedings. Such powers should also include the power to impose a temporary or definitive limitation, including a ban, on processing. Member States may specify other tasks related to the protection of personal data under this Regulation. The powers of supervisory authorities should be exercised in accordance with appropriate procedural safeguards set out in Union and Member State law, impartially, fairly and within a reasonable time. In particular each measure should be appropriate, necessary and proportionate in view of ensuring compliance with this Regulation, taking into account the circumstances of each individual case, respect the right of every person to be heard before any individual measure which would affect him or her adversely is taken and avoid superfluous costs and excessive inconveniences for the persons concerned. Investigatory powers as regards access to premises should be exercised in accordance with specific requirements in Member State procedural law, such as the requirement to obtain a prior judicial authorisation. Each legally binding measure of the supervisory authority should be in writing, be clear and unambiguous, indicate the supervisory authority which has issued the measure, the date of issue of the measure, bear the signature of the head, or a member of the supervisory authority authorised by him or her, give the reasons for the measure, and refer to the right of an effective remedy. This should not preclude additional requirements pursuant to Member State procedural law. The adoption of a legally binding decision implies that it may give rise to judicial review in the Member State of the supervisory authority that adopted the decision.
- (130) Where the supervisory authority with which the complaint has been lodged is not the lead supervisory authority, the lead supervisory authority should closely cooperate with the supervisory authority with which the complaint has been lodged in accordance with the provisions on cooperation and consistency laid down in this Regulation. In such cases, the lead supervisory authority should, when taking measures intended to produce legal effects, including the imposition of administrative fines, take utmost account of the view of the supervisory authority with which the complaint has been lodged and which should remain competent to carry out any investigation on the territory of its own Member State in liaison with the competent supervisory authority.
- (131) Where another supervisory authority should act as a lead supervisory authority for the processing activities of the controller or processor but the concrete subject matter of

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a complaint or the possible infringement concerns only processing activities of the controller or processor in the Member State where the complaint has been lodged or the possible infringement detected and the matter does not substantially affect or is not likely to substantially affect data subjects in other Member States, the supervisory authority receiving a complaint or detecting or being informed otherwise of situations that entail possible infringements of this Regulation should seek an amicable settlement with the controller and, if this proves unsuccessful, exercise its full range of powers. This should include: specific processing carried out in the territory of the Member State of the supervisory authority or with regard to data subjects on the territory of that Member State; processing that is carried out in the context of an offer of goods or services specifically aimed at data subjects in the territory of the Member State of the supervisory authority; or processing that has to be assessed taking into account relevant legal obligations under Member State law.

- (132) Awareness-raising activities by supervisory authorities addressed to the public should include specific measures directed at controllers and processors, including micro, small and medium-sized enterprises, as well as natural persons in particular in the educational context.
- (133) The supervisory authorities should assist each other in performing their tasks and provide mutual assistance, so as to ensure the consistent application and enforcement of this Regulation in the internal market. A supervisory authority requesting mutual assistance may adopt a provisional measure if it receives no response to a request for mutual assistance within one month of the receipt of that request by the other supervisory authority.
- (134) Each supervisory authority should, where appropriate, participate in joint operations with other supervisory authorities. The requested supervisory authority should be obliged to respond to the request within a specified time period.
- (135) In order to ensure the consistent application of this Regulation throughout the Union, a consistency mechanism for cooperation between the supervisory authorities should be established. That mechanism should in particular apply where a supervisory authority intends to adopt a measure intended to produce legal effects as regards processing operations which substantially affect a significant number of data subjects in several Member States. It should also apply where any supervisory authority concerned or the Commission requests that such matter should be handled in the consistency mechanism. That mechanism should be without prejudice to any measures that the Commission may take in the exercise of its powers under the Treaties.
- (136) In applying the consistency mechanism, the Board should, within a determined period of time, issue an opinion, if a majority of its members so decides or if so requested by any supervisory authority concerned or the Commission. The Board should also be empowered to adopt legally binding decisions where there are disputes between supervisory authorities. For that purpose, it should issue, in principle by a two-thirds majority of its members, legally binding decisions in clearly specified cases where there are conflicting views among supervisory authorities, in particular in the cooperation mechanism between the lead supervisory authority and supervisory

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authorities concerned on the merits of the case, in particular whether there is an infringement of this Regulation.

- (137) There may be an urgent need to act in order to protect the rights and freedoms of data subjects, in particular when the danger exists that the enforcement of a right of a data subject could be considerably impeded. A supervisory authority should therefore be able to adopt duly justified provisional measures on its territory with a specified period of validity which should not exceed three months.
- (138) The application of such mechanism should be a condition for the lawfulness of a measure intended to produce legal effects by a supervisory authority in those cases where its application is mandatory. In other cases of cross-border relevance, the cooperation mechanism between the lead supervisory authority and supervisory authorities concerned should be applied and mutual assistance and joint operations might be carried out between the supervisory authorities concerned on a bilateral or multilateral basis without triggering the consistency mechanism.
- (139) In order to promote the consistent application of this Regulation, the Board should be set up as an independent body of the Union. To fulfil its objectives, the Board should have legal personality. The Board should be represented by its Chair. It should replace the Working Party on the Protection of Individuals with Regard to the Processing of Personal Data established by Directive 95/46/EC. It should consist of the head of a supervisory authority of each Member State and the European Data Protection Supervisor or their respective representatives. The Commission should participate in the Board's activities without voting rights and the European Data Protection Supervisor should have specific voting rights. The Board should contribute to the consistent application of this Regulation throughout the Union, including by advising the Commission, in particular on the level of protection in third countries or international organisations, and promoting cooperation of the supervisory authorities throughout the Union. The Board should act independently when performing its tasks.
- (140) The Board should be assisted by a secretariat provided by the European Data Protection Supervisor. The staff of the European Data Protection Supervisor involved in carrying out the tasks conferred on the Board by this Regulation should perform its tasks exclusively under the instructions of, and report to, the Chair of the Board.
- (141) Every data subject should have the right to lodge a complaint with a single supervisory authority, in particular in the Member State of his or her habitual residence, and the right to an effective judicial remedy in accordance with Article 47 of the Charter if the data subject considers that his or her rights under this Regulation are infringed or where the supervisory authority does not act on a complaint, partially or wholly rejects or dismisses a complaint or does not act where such action is necessary to protect the rights of the data subject. The investigation following a complaint should be carried out, subject to judicial review, to the extent that is appropriate in the specific case. The supervisory authority should inform the data subject of the progress and the outcome of the complaint within a reasonable period. If the case requires further investigation or coordination with another supervisory authority, intermediate information should be given to the data subject. In order to facilitate the submission of complaints, each

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supervisory authority should take measures such as providing a complaint submission form which can also be completed electronically, without excluding other means of communication.

(142) Where a data subject considers that his or her rights under this Regulation are infringed, he or she should have the right to mandate a not-for-profit body, organisation or association which is constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest and is active in the field of the protection of personal data to lodge a complaint on his or her behalf with a supervisory authority, exercise the right to a judicial remedy on behalf of data subjects or, if provided for in Member State law, exercise the right to receive compensation on behalf of data subjects. A Member State may provide for such a body, organisation or association to have the right to lodge a complaint in that Member State, independently of a data subject's mandate, and the right to an effective judicial remedy where it has reasons to consider that the rights of a data subject have been infringed as a result of the processing of personal data which infringes this Regulation. That body, organisation or association may not be allowed to claim compensation on a data subject's behalf independently of the data subject's mandate.

(143) Any natural or legal person has the right to bring an action for annulment of decisions of the Board before the Court of Justice under the conditions provided for in Article 263 TFEU. As addressees of such decisions, the supervisory authorities concerned which wish to challenge them have to bring action within two months of being notified of them, in accordance with Article 263 TFEU. Where decisions of the Board are of direct and individual concern to a controller, processor or complainant, the latter may bring an action for annulment against those decisions within two months of their publication on the website of the Board, in accordance with Article 263 TFEU. Without prejudice to this right under Article 263 TFEU, each natural or legal person should have an effective judicial remedy before the competent national court against a decision of a supervisory authority which produces legal effects concerning that person. Such a decision concerns in particular the exercise of investigative, corrective and authorisation powers by the supervisory authority or the dismissal or rejection of complaints. However, the right to an effective judicial remedy does not encompass measures taken by supervisory authorities which are not legally binding, such as opinions issued by or advice provided by the supervisory authority. Proceedings against a supervisory authority should be brought before the courts of the Member State where the supervisory authority is established and should be conducted in accordance with that Member State's procedural law. Those courts should exercise full jurisdiction, which should include jurisdiction to examine all questions of fact and law relevant to the dispute before them.

Where a complaint has been rejected or dismissed by a supervisory authority, the complainant may bring proceedings before the courts in the same Member State. In the context of judicial remedies relating to the application of this Regulation, national courts which consider a decision on the question necessary to enable them to give judgment, may, or in the case provided for in Article 267 TFEU, must, request the Court of Justice to give a preliminary ruling on the interpretation of Union law, including

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this Regulation. Furthermore, where a decision of a supervisory authority implementing a decision of the Board is challenged before a national court and the validity of the decision of the Board is at issue, that national court does not have the power to declare the Board's decision invalid but must refer the question of validity to the Court of Justice in accordance with Article 267 TFEU as interpreted by the Court of Justice, where it considers the decision invalid. However, a national court may not refer a question on the validity of the decision of the Board at the request of a natural or legal person which had the opportunity to bring an action for annulment of that decision, in particular if it was directly and individually concerned by that decision, but had not done so within the period laid down in Article 263 TFEU.

- (144) Where a court seized of proceedings against a decision by a supervisory authority has reason to believe that proceedings concerning the same processing, such as the same subject matter as regards processing by the same controller or processor, or the same cause of action, are brought before a competent court in another Member State, it should contact that court in order to confirm the existence of such related proceedings. If related proceedings are pending before a court in another Member State, any court other than the court first seized may stay its proceedings or may, on request of one of the parties, decline jurisdiction in favour of the court first seized if that court has jurisdiction over the proceedings in question and its law permits the consolidation of such related proceedings. Proceedings are deemed to be related where they are so closely connected that it is expedient to hear and determine them together in order to avoid the risk of irreconcilable judgments resulting from separate proceedings.
- (145) For proceedings against a controller or processor, the plaintiff should have the choice to bring the action before the courts of the Member States where the controller or processor has an establishment or where the data subject resides, unless the controller is a public authority of a Member State acting in the exercise of its public powers.
- (146) The controller or processor should compensate any damage which a person may suffer as a result of processing that infringes this Regulation. The controller or processor should be exempt from liability if it proves that it is not in any way responsible for the damage. The concept of damage should be broadly interpreted in the light of the case-law of the Court of Justice in a manner which fully reflects the objectives of this Regulation. This is without prejudice to any claims for damage deriving from the violation of other rules in Union or Member State law. Processing that infringes this Regulation also includes processing that infringes delegated and implementing acts adopted in accordance with this Regulation and Member State law specifying rules of this Regulation. Data subjects should receive full and effective compensation for the damage they have suffered. Where controllers or processors are involved in the same processing, each controller or processor should be held liable for the entire damage. However, where they are joined to the same judicial proceedings, in accordance with Member State law, compensation may be apportioned according to the responsibility of each controller or processor for the damage caused by the processing, provided that full and effective compensation of the data subject who suffered the damage is ensured. Any controller or processor which has paid full compensation may subsequently institute

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recourse proceedings against other controllers or processors involved in the same processing.

- (147) Where specific rules on jurisdiction are contained in this Regulation, in particular as regards proceedings seeking a judicial remedy including compensation, against a controller or processor, general jurisdiction rules such as those of Regulation (EU) No 1215/2012 of the European Parliament and of the Council<sup>(13)</sup> should not prejudice the application of such specific rules.
- (148) In order to strengthen the enforcement of the rules of this Regulation, penalties including administrative fines should be imposed for any infringement of this Regulation, in addition to, or instead of appropriate measures imposed by the supervisory authority pursuant to this Regulation. In a case of a minor infringement or if the fine likely to be imposed would constitute a disproportionate burden to a natural person, a reprimand may be issued instead of a fine. Due regard should however be given to the nature, gravity and duration of the infringement, the intentional character of the infringement, actions taken to mitigate the damage suffered, degree of responsibility or any relevant previous infringements, the manner in which the infringement became known to the supervisory authority, compliance with measures ordered against the controller or processor, adherence to a code of conduct and any other aggravating or mitigating factor. The imposition of penalties including administrative fines should be subject to appropriate procedural safeguards in accordance with the general principles of Union law and the Charter, including effective judicial protection and due process.
- (149) Member States should be able to lay down the rules on criminal penalties for infringements of this Regulation, including for infringements of national rules adopted pursuant to and within the limits of this Regulation. Those criminal penalties may also allow for the deprivation of the profits obtained through infringements of this Regulation. However, the imposition of criminal penalties for infringements of such national rules and of administrative penalties should not lead to a breach of the principle of *ne bis in idem*, as interpreted by the Court of Justice.
- (150) In order to strengthen and harmonise administrative penalties for infringements of this Regulation, each supervisory authority should have the power to impose administrative fines. This Regulation should indicate infringements and the upper limit and criteria for setting the related administrative fines, which should be determined by the competent supervisory authority in each individual case, taking into account all relevant circumstances of the specific situation, with due regard in particular to the nature, gravity and duration of the infringement and of its consequences and the measures taken to ensure compliance with the obligations under this Regulation and to prevent or mitigate the consequences of the infringement. Where administrative fines are imposed on an undertaking, an undertaking should be understood to be an undertaking in accordance with Articles 101 and 102 TFEU for those purposes. Where administrative fines are imposed on persons that are not an undertaking, the supervisory authority should take account of the general level of income in the Member State as well as the economic situation of the person in considering the appropriate amount of the fine. The consistency mechanism may also be used to promote a consistent application of

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administrative fines. It should be for the Member States to determine whether and to which extent public authorities should be subject to administrative fines. Imposing an administrative fine or giving a warning does not affect the application of other powers of the supervisory authorities or of other penalties under this Regulation.

- (151) The legal systems of Denmark and Estonia do not allow for administrative fines as set out in this Regulation. The rules on administrative fines may be applied in such a manner that in Denmark the fine is imposed by competent national courts as a criminal penalty and in Estonia the fine is imposed by the supervisory authority in the framework of a misdemeanour procedure, provided that such an application of the rules in those Member States has an equivalent effect to administrative fines imposed by supervisory authorities. Therefore the competent national courts should take into account the recommendation by the supervisory authority initiating the fine. In any event, the fines imposed should be effective, proportionate and dissuasive.
- (152) Where this Regulation does not harmonise administrative penalties or where necessary in other cases, for example in cases of serious infringements of this Regulation, Member States should implement a system which provides for effective, proportionate and dissuasive penalties. The nature of such penalties, criminal or administrative, should be determined by Member State law.
- (153) Member States law should reconcile the rules governing freedom of expression and information, including journalistic, academic, artistic and or literary expression with the right to the protection of personal data pursuant to this Regulation. The processing of personal data solely for journalistic purposes, or for the purposes of academic, artistic or literary expression should be subject to derogations or exemptions from certain provisions of this Regulation if necessary to reconcile the right to the protection of personal data with the right to freedom of expression and information, as enshrined in Article 11 of the Charter. This should apply in particular to the processing of personal data in the audiovisual field and in news archives and press libraries. Therefore, Member States should adopt legislative measures which lay down the exemptions and derogations necessary for the purpose of balancing those fundamental rights. Member States should adopt such exemptions and derogations on general principles, the rights of the data subject, the controller and the processor, the transfer of personal data to third countries or international organisations, the independent supervisory authorities, cooperation and consistency, and specific data-processing situations. Where such exemptions or derogations differ from one Member State to another, the law of the Member State to which the controller is subject should apply. In order to take account of the importance of the right to freedom of expression in every democratic society, it is necessary to interpret notions relating to that freedom, such as journalism, broadly.
- (154) This Regulation allows the principle of public access to official documents to be taken into account when applying this Regulation. Public access to official documents may be considered to be in the public interest. Personal data in documents held by a public authority or a public body should be able to be publicly disclosed by that authority or body if the disclosure is provided for by Union or Member State law to which the public authority or public body is subject. Such laws should reconcile public access to official

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documents and the reuse of public sector information with the right to the protection of personal data and may therefore provide for the necessary reconciliation with the right to the protection of personal data pursuant to this Regulation. The reference to public authorities and bodies should in that context include all authorities or other bodies covered by Member State law on public access to documents. Directive 2003/98/EC of the European Parliament and of the Council<sup>(14)</sup> leaves intact and in no way affects the level of protection of natural persons with regard to the processing of personal data under the provisions of Union and Member State law, and in particular does not alter the obligations and rights set out in this Regulation. In particular, that Directive should not apply to documents to which access is excluded or restricted by virtue of the access regimes on the grounds of protection of personal data, and parts of documents accessible by virtue of those regimes which contain personal data the re-use of which has been provided for by law as being incompatible with the law concerning the protection of natural persons with regard to the processing of personal data.

- (155) Member State law or collective agreements, including ‘works agreements’, may provide for specific rules on the processing of employees' personal data in the employment context, in particular for the conditions under which personal data in the employment context may be processed on the basis of the consent of the employee, the purposes of the recruitment, the performance of the contract of employment, including discharge of obligations laid down by law or by collective agreements, management, planning and organisation of work, equality and diversity in the workplace, health and safety at work, and for the purposes of the exercise and enjoyment, on an individual or collective basis, of rights and benefits related to employment, and for the purpose of the termination of the employment relationship.
- (156) The processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be subject to appropriate safeguards for the rights and freedoms of the data subject pursuant to this Regulation. Those safeguards should ensure that technical and organisational measures are in place in order to ensure, in particular, the principle of data minimisation. The further processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which do not permit or no longer permit the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data). Member States should provide for appropriate safeguards for the processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. Member States should be authorised to provide, under specific conditions and subject to appropriate safeguards for data subjects, specifications and derogations with regard to the information requirements and rights to rectification, to erasure, to be forgotten, to restriction of processing, to data portability, and to object when processing personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. The conditions and safeguards in question may entail specific procedures for data subjects to exercise those rights if this is appropriate in the light of the purposes sought by the specific



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processing along with technical and organisational measures aimed at minimising the processing of personal data in pursuance of the proportionality and necessity principles. The processing of personal data for scientific purposes should also comply with other relevant legislation such as on clinical trials.

- (157) By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about the long-term correlation of a number of social conditions such as unemployment and education with other life conditions. Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law.
- (158) Where personal data are processed for archiving purposes, this Regulation should also apply to that processing, bearing in mind that this Regulation should not apply to deceased persons. Public authorities or public or private bodies that hold records of public interest should be services which, pursuant to Union or Member State law, have a legal obligation to acquire, preserve, appraise, arrange, describe, communicate, promote, disseminate and provide access to records of enduring value for general public interest. Member States should also be authorised to provide for the further processing of personal data for archiving purposes, for example with a view to providing specific information related to the political behaviour under former totalitarian state regimes, genocide, crimes against humanity, in particular the Holocaust, or war crimes.
- (159) Where personal data are processed for scientific research purposes, this Regulation should also apply to that processing. For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research. In addition, it should take into account the Union's objective under Article 179(1) TFEU of achieving a European Research Area. Scientific research purposes should also include studies conducted in the public interest in the area of public health. To meet the specificities of processing personal data for scientific research purposes, specific conditions should apply in particular as regards the publication or otherwise disclosure of personal data in the context of scientific research purposes. If the result of scientific research in particular in the health context gives reason for further measures in the interest of the data subject, the general rules of this Regulation should apply in view of those measures.
- (160) Where personal data are processed for historical research purposes, this Regulation should also apply to that processing. This should also include historical research and research for genealogical purposes, bearing in mind that this Regulation should not apply to deceased persons.

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- (161) For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council<sup>(15)</sup> should apply.
- (162) Where personal data are processed for statistical purposes, this Regulation should apply to that processing. Union or Member State law should, within the limits of this Regulation, determine statistical content, control of access, specifications for the processing of personal data for statistical purposes and appropriate measures to safeguard the rights and freedoms of the data subject and for ensuring statistical confidentiality. Statistical purposes mean any operation of collection and the processing of personal data necessary for statistical surveys or for the production of statistical results. Those statistical results may further be used for different purposes, including a scientific research purpose. The statistical purpose implies that the result of processing for statistical purposes is not personal data, but aggregate data, and that this result or the personal data are not used in support of measures or decisions regarding any particular natural person.
- (163) The confidential information which the Union and national statistical authorities collect for the production of official European and official national statistics should be protected. European statistics should be developed, produced and disseminated in accordance with the statistical principles as set out in Article 338(2) TFEU, while national statistics should also comply with Member State law. Regulation (EC) No 223/2009 of the European Parliament and of the Council<sup>(16)</sup> provides further specifications on statistical confidentiality for European statistics.
- (164) As regards the powers of the supervisory authorities to obtain from the controller or processor access to personal data and access to their premises, Member States may adopt by law, within the limits of this Regulation, specific rules in order to safeguard the professional or other equivalent secrecy obligations, in so far as necessary to reconcile the right to the protection of personal data with an obligation of professional secrecy. This is without prejudice to existing Member State obligations to adopt rules on professional secrecy where required by Union law.
- (165) This Regulation respects and does not prejudice the status under existing constitutional law of churches and religious associations or communities in the Member States, as recognised in Article 17 TFEU.
- (166) In order to fulfil the objectives of this Regulation, namely to protect the fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data and to ensure the free movement of personal data within the Union, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission. In particular, delegated acts should be adopted in respect of criteria and requirements for certification mechanisms, information to be presented by standardised icons and procedures for providing such icons. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

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- (167) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission when provided for by this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011. In that context, the Commission should consider specific measures for micro, small and medium-sized enterprises.
- (168) The examination procedure should be used for the adoption of implementing acts on standard contractual clauses between controllers and processors and between processors; codes of conduct; technical standards and mechanisms for certification; the adequate level of protection afforded by a third country, a territory or a specified sector within that third country, or an international organisation; standard protection clauses; formats and procedures for the exchange of information by electronic means between controllers, processors and supervisory authorities for binding corporate rules; mutual assistance; and arrangements for the exchange of information by electronic means between supervisory authorities, and between supervisory authorities and the Board.
- (169) The Commission should adopt immediately applicable implementing acts where available evidence reveals that a third country, a territory or a specified sector within that third country, or an international organisation does not ensure an adequate level of protection, and imperative grounds of urgency so require.
- (170) Since the objective of this Regulation, namely to ensure an equivalent level of protection of natural persons and the free flow of personal data throughout the Union, cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union (TEU). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (171) Directive 95/46/EC should be repealed by this Regulation. Processing already under way on the date of application of this Regulation should be brought into conformity with this Regulation within the period of two years after which this Regulation enters into force. Where processing is based on consent pursuant to Directive 95/46/EC, it is not necessary for the data subject to give his or her consent again if the manner in which the consent has been given is in line with the conditions of this Regulation, so as to allow the controller to continue such processing after the date of application of this Regulation. Commission decisions adopted and authorisations by supervisory authorities based on Directive 95/46/EC remain in force until amended, replaced or repealed.
- (172) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 7 March 2012<sup>(17)</sup>.
- (173) This Regulation should apply to all matters concerning the protection of fundamental rights and freedoms *vis-à-vis* the processing of personal data which are not subject to specific obligations with the same objective set out in Directive 2002/58/EC of the

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European Parliament and of the Council<sup>(18)</sup>, including the obligations on the controller and the rights of natural persons. In order to clarify the relationship between this Regulation and Directive 2002/58/EC, that Directive should be amended accordingly. Once this Regulation is adopted, Directive 2002/58/EC should be reviewed in particular in order to ensure consistency with this Regulation,

HAVE ADOPTED THIS REGULATION:

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- (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](#)).
- (5) 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](#)).
- (6) 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](#)).
- (7) 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).
- (8) 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](#)).
- (9) 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](#)).
- (10) Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts ([OJ L 95, 21.4.1993, p. 29](#)).
- (11) 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](#)).
- (12) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13](#)).
- (13) Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters ([OJ L 351, 20.12.2012, p. 1](#)).
- (14) Directive 2003/98/EC of the European Parliament and of the Council of 17 November 2003 on the re-use of public sector information ([OJ L 345, 31.12.2003, p. 90](#)).
- (15) 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](#)).
- (16) Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities ([OJ L 87, 31.3.2009, p. 164](#)).
- (17) [OJ C 192, 30.6.2012, p. 7.](#)
- (18) 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](#)).

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