EUROPEAN COMMISSION

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2012/0011 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)

(Text with EEA relevance)

{SEC(2012) 72 final}
{SEC(2012) 73 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

This explanatory memorandum presents in further detail the proposed new legal framework for the protection of personal data in the EU as set out in Communication COM (2012) 9 final[1]. The proposed new legal framework consists of two legislative proposals:

- a proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), and

- a proposal for a Directive of the European Parliament and of the Council on the protection of individuals 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[2].

This explanatory memorandum concerns the legislative proposal for a General Data Protection Regulation.

The centrepiece of existing EU legislation on personal data protection, Directive 95/46/EC[3], was adopted in 1995 with two objectives in mind: to protect the fundamental right to data protection and to guarantee the free flow of personal data between Member States. It was complemented by Framework Decision 2008/977/JHA as a general instrument at Union level for the protection of personal data in the areas of police co-operation and judicial co-operation in criminal matters[4].

Rapid technological developments have brought new challenges for the protection of personal data. The scale of data sharing and collecting has increased dramatically. Technology allows both private companies and public authorities to make use of personal data on an unprecedented scale in order to pursue their activities. Individuals increasingly make personal information available publicly and globally. Technology has transformed both the economy and social life.

Building trust in the online environment is key to economic development. Lack of trust makes consumers hesitate to buy online and adopt new services. This risks slowing down the development of innovative uses of new technologies. Personal data protection therefore plays

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1 "Safeguarding Privacy in a Connected World – A European Data Protection Framework for the 21st Century" COM(2012) 9 final.

2 COM(2012) 10 final.

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

4 Council Framework Decision 2008/977/JHA of 27 November 2008 on the protection of personal data processed in the framework of police and judicial cooperation in criminal matters, OJ L 350, 30.12.2008, p. 60 ('Framework Decision').

a central role in the Digital Agenda for Europe[5], and more generally in the Europe 2020 Strategy[6].

Article 16(1) of Treaty on the Functioning of the European Union (TFEU), as introduced by the Lisbon Treaty, establishes the principle that everyone has the right to the protection of personal data concerning him or her. Moreover, with Article 16(2) TFEU, the Lisbon Treaty introduced a specific legal basis for the adoption of rules on the protection of personal data. Article 8 of the Charter of Fundamental Rights of the EU enshrines protection of personal data as a fundamental right.

The European Council invited the Commission to evaluate the functioning of EU instruments on data protection and to present, where necessary, further legislative and non-legislative initiatives[7]. In its resolution on the Stockholm Programme, the European Parliament[8] welcomed a comprehensive data protection scheme in the EU and among others called for the revision of the Framework Decision. The Commission stressed in its Action Plan implementing the Stockholm Programme[9] the need to ensure that the fundamental right to personal data protection is consistently applied in the context of all EU policies.

In its Communication on "A comprehensive approach on personal data protection in the European Union"[10], the Commission concluded that the EU needs a more comprehensive and coherent policy on the fundamental right to personal data protection.

The current framework remains sound as far as its objectives and principles are concerned, but it has not prevented fragmentation in the way personal data protection is implemented across the Union, legal uncertainty and a widespread public perception that there are significant risks associated notably with online activity[11]. This is why it is time to build a stronger and more coherent data protection framework in the EU, backed by strong enforcement that will allow the digital economy to develop across the internal market, put individuals in control of their own data and reinforce legal and practical certainty for economic operators and public authorities.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT

This initiative is the result of extensive consultations with all major stakeholders on a review of the current legal framework for the protection of personal data, which lasted for more than two years and included a high level conference in May 2009[12] and two phases of public consultation:

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5 COM(2010)245 final.

6 COM(2010)2020 final.

7 "The Stockholm Programme — An open and secure Europe serving and protecting citizens", OJ C 115, 4.5.2010, p.1.

8 Resolution of the European Parliament on the on the Communication from the Commission to the European Parliament and the Council – An area of freedom, security and justice serving the citizen – Stockholm programme adopted 25 November 2009 (P7_TA(2009)0090).

9 COM(2010)171 final.

10 COM(2010)609 final.

11 Special Eurobarometer (EB) 359, *Data Protection and Electronic Identity in the EU* (2011): http://ec.europa.eu/public_opinion/archives/ebs/ebs_359_en.pdf.

12 http://ec.europa.eu/justice/newsroom/data-protection/events/090519_en.htm.

- From 9 July to 31 December 2009, the *Consultation on the legal framework for the fundamental right to the protection of personal data.* The Commission received 168 responses, 127 from individuals, business organisations and associations and 12 from public authorities.[13]

- From 4 November 2010 to 15 January 2011, the *Consultation on the Commission's comprehensive approach on personal data protection in the European Union.* The Commission received 305 responses, of which 54 from citizens, 31 from public authorities and 220 from private organisations, in particular business associations and non-governmental organisations.[14]

Targeted consultations were also conducted with key stakeholders; specific events were organised in June and July 2010 with Member State authorities and with private sector stakeholders, as well as privacy, data protection and consumers' organisations[15]. In November 2010, European Commission's Vice-President Reding organised a roundtable on the data protection reform. On 28 January 2011 (Data Protection Day), the European Commission and the Council of Europe co-organised a high level conference to discuss issues related to the reform of the EU legal framework as well as to the need for common data protection standards worldwide[16]. Two conferences on data protection were hosted by the Hungarian and Polish Presidencies of the Council on 16-17 June 2011 and on 21 September 2011 respectively.

Dedicated workshops and seminars on specific issues were held throughout 2011. In January ENISA[17] organised a workshop on data breach notifications in Europe[18]. In February, the Commission convened a workshop with Member States' authorities to discuss data protection issues in the area of police co-operation and judicial co-operation in criminal matters, including the implementation of the Framework Decision, and the Fundamental Rights Agency held a stakeholder consultation meeting on "Data Protection and Privacy". A discussion on key issues of the reform was held on 13 July 2011 with national Data Protection Authorities. EU citizens were consulted through a Eurobarometer survey held in November-December 2010[19]. A number of studies were also launched.[20] The "Article 29 Working Party"[21] provided several opinions and useful input to the Commission[22]. The European Data

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13 The non-confidential contributions can be consulted on the Commission's website: http://ec.europa.eu/justice/newsroom/data-protection/opinion/090709_en.htm.

14 The non-confidential contributions can be consulted on the Commission's website: http://ec.europa.eu/justice/newsroom/data-protection/opinion/101104_en.htm.

15 http://ec.europa.eu/justice/newsroom/data-protection/events/100701_en.htm.

16 http://www.coe.int/t/dghl/standardsetting/dataprotection/Data_protection_day2011_en.asp.

17 European Network and Information Security Agency, dealing with security issues related to communication networks and information systems.

18 See http://www.enisa.europa.eu/act/it/data-breach-notification.

19 Special Eurobarometer (EB) 359, *Data Protection and Electronic Identity in the EU* (2011): http://ec.europa.eu/public_opinion/archives/ebs/ebs_359_en.pdf.

20 See the *Study on the economic benefits of privacy enhancing technologies* and the *Comparative study on different approaches to new privacy challenges, in particular in the light of technological developments*, January 2010 (http://ec.europa.eu/justice/policies/privacy/docs/studies/new_privacy_challenges/final_report_en.pdf)..

21 The Working Party was set up in 1996 (by Article 29 of Directive 95/46/EC) with advisory status and composed of representatives of national Data Protection Supervisory Authorities (DPAs), the European Data Protection Supervisor (EDPS) and the Commission. For more information on its activities see http://ec.europa.eu/justice/policies/privacy/workinggroup/index_en.htm.

Protection Supervisor also issued a comprehensive opinion on the issues raised in the Commission's November 2010 Communication[23].

The European Parliament approved by its resolution of 6 July 2011 a report that supported the Commission's approach to reforming the data protection framework.[24] The Council of the European Union adopted conclusions on 24 February 2011 in which it broadly supports the Commission's intention to reform the data protection framework and agrees with many elements of the Commission's approach. The European Economic and Social Committee likewise supported the Commission's aim to ensure a more consistent application of EU data [25]protection rules across all Member States an appropriate revision of Directive 95/46/EC.[26]

During the consultations on the comprehensive approach, a large majority of stakeholders agreed that the general principles remain valid but that there is a need to adapt the current framework in order to better respond to challenges posed by the rapid development of new technologies (particularly online) and increasing globalisation, while maintaining the technological neutrality of the legal framework. Heavy criticism has been expressed regarding the current fragmentation of personal data protection in the Union, in particular by economic stakeholders who asked for increased legal certainty and harmonisation of the rules on the protection of personal data. The complexity of the rules on international transfers of personal data is considered as constituting a substantial impediment to their operations as they regularly need to transfer personal data from the EU to other parts of the world.

In line with its "Better Regulation" policy, the Commission conducted an impact assessment of policy alternatives. The impact assessment was based on the three policy objectives of improving the internal market dimension of data protection, making the exercise of data protection rights by individuals more effective and creating a comprehensive and coherent framework covering all areas of Union competence, including police co-operation and judicial co-operation in criminal matters. Three policy options of different degrees of intervention were assessed: the first option consisted of minimal legislative amendments and the use of interpretative Communications and policy support measures such as funding programmes and technical tools; the second option comprised a set of legislative provisions addressing each of the issues identified in the analysis and the third option was the centralisation of data protection at EU level through precise and detailed rules for all sectors and the establishment of an EU agency for monitoring and enforcement of the provisions.

According to the Commission's established methodology, each policy option was assessed, with the help of an Interservice steering group, against its effectiveness to achieve the policy objectives, its economic impact on stakeholders (including on the budget of the EU

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22 See in particular the following opinions: on the "Future of Privacy" (2009, WP 168); on the concepts of "controller" and "processor" (1/2010, WP 169); on online behavioural advertising (2/2010, WP 171); on the principle of accountability (3/2010, WP 173); on applicable law (8/2010, WP 179); and on consent (15/2011, WP 187). Upon the Commission's request, it adopted also the three following Advice Papers: on notifications, on sensitive data and on the practical implementation of Article 28(6) of the Data Protection Directive. They can all be accessed at: http://ec.europa.eu/justice/data-protection/article-29/documentation/index_en.htm.

23 Available on the EDPS website: http://www.edps.europa.eu/EDPSWEB.

24 EP resolution of 6 July 2011 on a comprehensive approach on personal data protection in the European Union (2011/2025(INI), http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2011-0323&language=EN&ring=A7-2011-0244 (rapporteur: MEP Axel Voss (EPP/DE).

25 SEC(2012)72.

26 CESE 999/2011.

institutions), its social impact and effect on fundamental rights. Environmental impacts were not observed. The analysis of the overall impact led to the development of the preferred policy option which is based on the second option with some elements from the other two options and incorporated in the present proposal. According to the impact assessment, its implementation will lead *inter alia* to considerable improvements regarding legal certainty for data controllers and citizens, reduction of administrative burden, consistency of data protection enforcement in the Union, the effective possibility of individuals to exercise their data protection rights to the protection of personal data within the EU and the efficiency of data protection supervision and enforcement. Implementation of the preferred policy options are also expected to contribute to the Commission's objective of simplification and reduction of administrative burden and to the objectives of the Digital Agenda for Europe, the Stockholm Action Plan and the Europe 2020 strategy.

The Impact Assessment Board delivered an opinion on the draft impact assessment on 9 September 2011. Following the IAB opinion, the following changes were made to the impact assessment:

- The objectives of the current legal framework (to what extent they were achieved, and to what extent they were not), as well as the objectives of the envisaged reform were clarified;
- More evidence and additional explanations/clarification were added to the problems' definition section;
- A section on proportionality was added;
- All calculations and estimations related to administrative burden in the baseline scenario and in the preferred option have been entirely reviewed and revised, and the relation between the costs of notifications and the overall fragmentation costs has been clarified (including Annex 10);
- Impacts on micro, small and medium enterprises, particularly of data protection officers and data protection impact assessments have been better specified.

The impact assessment report and an executive summary are published with the proposals.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. Legal Basis

This proposal is based on Article 16 TFEU, which is the new legal basis for the adoption of data protection rules introduced by the Lisbon Treaty. This provision allows the adoption of rules relating to the protection of individuals with regard to the processing of personal data by Member States when carrying out activities which fall within the scope of Union law. It also allows the adoption of rules relating to the free movement of personal data, including personal data processed by Member States or private parties.

A Regulation is considered to be the most appropriate legal instrument to define the framework for the protection of personal data in the Union. The direct applicability of a Regulation in accordance with Article 288 TFEU will reduce legal fragmentation and provide greater legal certainty by introducing a harmonised set of core rules, improving the protection

of fundamental rights of individuals and contributing to the functioning of the Internal Market.

The reference to Article 114(1) TFEU is only necessary for amending Directive 2002/58/EC to the extent that that Directive also provides for the protection of the legitimate interests of subscribers who are legal persons.

3.2. Subsidiarity and proportionality

According to the principle of subsidiarity (Article 5(3) TEU), action at Union level shall be taken only if and in so far as the objectives envisaged cannot be achieved sufficiently by Member States, but can rather, by reason of the scale or effects of the proposed action, be better achieved by the Union. In the light of the problems outlined above, the analysis of subsidiarity indicates the necessity of EU-level action on the following grounds:

- The right to the protection of personal data, enshrined in Article 8 of the Charter of Fundamental Rights, requires the same level of data protection throughout the Union. The absence of common EU rules would create the risk of different levels of protection in the Member States and create restrictions on cross-border flows of personal data between Member States with different standards.

- Personal data are transferred across national boundaries, both internal and external borders, at rapidly increasing rates. In addition, there are practical challenges to enforcing data protection legislation and a need for co-operation between Member States and their authorities, which needs to be organised at EU level to ensure unity of application of Union law. The EU is also best placed to ensure effectively and consistently the same level of protection for individuals when their personal data are transferred to third countries.

- Member States cannot alone reduce the problems in the current situation, particularly those due to the fragmentation in national legislations. Thus, there is a specific need to establish a harmonised and coherent framework allowing for a smooth transfer of personal data across borders within the EU while ensuring effective protection for all individuals across the EU.

- The proposed EU legislative actions will be more effective than similar actions at the level of Member States because of the nature and scale of the problems, which are not confined to the level of one or several Member States.

The principle of proportionality requires that any intervention is targeted and does not go beyond what is necessary to achieve the objectives. This principle has guided the preparation of this proposal from the identification and evaluation of alternative policy options to the drafting of the legislative proposal.

3.3. Summary of fundamental rights issues

The right to protection of personal data is established by Article 8 of the Charter and Article 16 TFEU and in Article 8 of the ECHR. As underlined by the Court of Justice of the EU[27], the right to the protection of personal data is not an absolute right, but must be considered in

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27 Court of Justice of the EU, judgment of 9.11.2010, Joined Cases C-92/09 and C-93/09 Volker und Markus Schecke and Eifert [2010] ECR I-0000.

relation to its function in society[28]. Data protection is closely linked to respect for private and family life protected by Article 7 of the Charter. This is reflected by Article 1(1) of Directive 95/46/EC which provides that Member States shall protect fundamental rights and freedoms of natural persons and in particular their right to privacy with respect of the processing of personal data.

Other potentially affected fundamental rights enshrined in the Charter are the following: freedom of expression (Article 11 of the Charter); freedom to conduct a business (Article 16); the right to property and in particular the protection of intellectual property (Article 17(2)); the prohibition of any discrimination amongst others on grounds such as race, ethnic origin, genetic features, religion or belief, political opinion or any other opinion, disability or sexual orientation (Article 21); the rights of the child (Article 24); the right to a high level of human health care (Article 35); the right of access to documents (Article 42); the right to an effective remedy and a fair trial (Article 47).

3.4. Detailed explanation of the proposal

3.4.1. CHAPTER I - GENERAL PROVISIONS

Article 1 defines subject matter of the Regulation, and, as in Article 1 of Directive 95/46/EC, sets out the two objectives of the Regulation.

Article 2 determines the material scope of the Regulation.

Article 3 determines the territorial scope of the Regulation.

Article 4 contains definitions of terms used in the Regulation. While some definitions are taken over from Directive 95/46/EC, others are modified, complemented with additional elements, or newly introduced ('personal data breach' based on Article 2(h) of the e-privacy Directive 2002/58/EC[29] as amended by Directive 2009/136/EC[30], 'genetic data', 'biometric data', 'data concerning health', 'main establishment', 'representative', 'enterprise', 'group of undertakings', 'binding corporate rules', and of a 'child' which is based on the United Nation's Convention on the Rights of the Child[31], and 'supervisory authority').

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28 In line with Article 52(1) of the Charter, limitations may be imposed on the exercise of the right to data protection as long as the limitations are provided for by law, respect the essence of the right and freedoms and, subject to the principle of proportionality, are necessary and genuinely meet objectives of general interest recognised by the European Union or the need to protect the rights and freedoms of others.

29 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, 31/07/2002, p. 37.

30 Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009 amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services, Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector and Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws Text with EEA relevance; OJ L 337 , 18.12.2009, p. 11.

31 Adopted and opened for signature, ratification and accession by the United Nations General Assembly resolution 44/25 of 20.11.1989.

In the definition of consent, the criterion 'explicit' is added to avoid confusing parallelism with 'unambiguous' consent and in order to have one single and consistent definition of consent, ensuring the awareness of the data subject that, and to what, he or she gives consent.

3.4.2. CHAPTER II - PRINCIPLES

Article 5 sets out the principles relating to personal data processing, which correspond to those in Article 6 of Directive 95/46/EC. Additional new elements are in particular the transparency principle, the clarification of the data minimisation principle and the establishment of a comprehensive responsibility and liability of the controller.

Article 6 sets out, based on Article 7 of Directive 95/46/EC, the criteria for lawful processing, which are further specified as regards the balance of interest criterion, and the compliance with legal obligations and public interest.

Article 7 clarifies the conditions for consent to be valid as a legal ground for lawful processing.

Article 8 sets out further conditions for the lawfulness of the processing of personal data of children in relation to information society services offered directly to them.

Article 9 sets out the general prohibition for processing special categories of personal data and the exceptions from this general rule, building on Article 8 of the Directive 95/46/EC.

Article 10 clarifies that the controller is not obliged to acquire additional information in order to identify the data subject for the sole purpose of complying with any provision of this Regulation.

3.4.3. CHAPTER III - RIGHTS OF THE DATA SUBJECT

3.4.3.1. Section 1 – Transparency and modalities

Article 11 introduces the obligation on controllers to provide transparent and easily accessible and understandable information, inspired in particular by the Madrid Resolution on international standards on the protection of personal data and privacy[32].

Article 12 obliges the controller to provide procedures and mechanism for exercising the data subject's rights, including means for electronic requests, requiring response to the data subject's request within a defined deadline, and the motivation of refusals.

Article 13 provides rights in relation to recipients, based on Article 12(c) of Directive 95/46/EC, extended to all recipients, including joint controllers and processors.

3.4.3.2. Section 2 – Information and access to data

Article 14 further specifies the controller's information obligations towards the data subject, building on Articles 10 and 11 of Directive 95/46/EC, providing additional information to the data subject, including on the storage period, the right to lodge a complaint, in relation to

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[32] Adopted by the International Conference of Data Protection and Privacy Commissioners on 5 November 2009. Cf. also Article 13(3) of the proposal for a Regulation on a Common European Sales Law (COM(2011)635final).

international transfers and to the source from which the data are originating. It also maintains the possible derogations in Directive 95/46/EC, e.g. there will be no such obligation if the recording or disclosure are expressly provided by law. This could apply for example in proceedings by competition authorities, tax or customs administrations, or services competent for social security matters.

Article 15 provides the data subject's right of access to their personal data, building on Article 12(a) of Directive 95/46/EC and adding new elements, such as to inform the data subjects of the storage period, and of the rights to rectification and to erasure and to lodge a complaint.

3.4.3.3. Section 3 – Rectification and erasure

Article 16 sets out the data subject's right to rectification, based on Article 12(b) of Directive 95/46/EC.

Article 17 provides the data subject's right to be forgotten and to erasure. It further elaborates and specifies the right of erasure provided for in Article 12(b) of Directive 95/46/EC and provides the conditions of the right to be forgotten, including the obligation of the controller which has made the personal data public to inform third parties on the data subject's request to erase any links to, or copy or replication of that personal data. It also integrates the right to have the processing restricted in certain cases, avoiding the ambiguous terminology "blocking".

Article 18 introduces the data subject's right to data portability, i.e. to transfer data from one electronic processing system to and into another, without being prevented from doing so by the controller. As a precondition and in order to further improve access of individuals to their personal data, it provides the right to obtain from the controller those data in a structured and commonly used electronic format.

3.4.3.4. Section 4 – Right to object and profiling

Article 19 provides for the data subject's rights to object. It is based on Article 14 of Directive 95/46/EC, with some modifications, including as regards the burden of proof and its application to direct marketing.

Article 20 concerns the data subject's right not to be subject to a measure based on profiling. It builds on, with modifications and additional safeguards, Article 15(1) of Directive 95/46 on automated individual decisions, and takes account of the Council of Europe's recommendation on profiling[33].

3.4.3.5. Section 5 – Restrictions

Article 21 clarifies the empowerment for the Union or Member States to maintain or introduce restrictions of principles laid down in Article 5 and of the data subject's rights laid down in Articles 11 to 20 and in Article 32. This provision is based on Article 13 of Directive 95/46/EC and on the requirements stemming from the Charter of Fundamental Rights and the European Convention for the Protection of Human Rights and Fundamental Freedoms, as interpreted by the Court of Justice of the EU and the European Court of Human Rights.

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[33] CM/Rec (2010)13.

3.4.4. CHAPTER IV - CONTROLLER AND PROCESSOR

3.4.4.1. Section 1 – General obligations

Article 22 takes account of the debate on a "principle of accountability" and describes in detail the obligation of responsibility of the controller to comply with this Regulation and to demonstrate this compliance, including by way of adoption of internal policies and mechanisms for ensuring such compliance.

Article 23 sets out the obligations of the controller arising from the principles of data protection by design and by default.

Article 24 on joint controllers clarifies the responsibilities of joint controllers as regards their internal relationship and towards the data subject.

Article 25 obliges under certain conditions controllers not established in the Union, where the Regulation applies to their processing activities, to designate a representative in the Union.

Article 26 clarifies the position and obligation of processors, partly based on Article 17(2) of Directive 95/46/EC, and adding new elements, including that a processor who processes data beyond the controller's instructions is to be considered as a joint controller.

Article 27 on the processing under the authority of the controller and processor is based on Article 16 of Directive 95/46/EC.

Article 28 introduces the obligation for controllers and processors to maintain documentation of the processing operations under their responsibility, instead of a general notification to the supervisory authority required by Articles 18(1) and 19 of Directive 95/46/EC.

Article 29 clarifies the obligations of the controller and the processor for the co-operation with the supervisory authority.

3.4.4.2. Section 2 – Data security

Article 30 obliges the controller and the processor to implement appropriate measures for the security of processing, based on Article 17(1) of Directive 95/46/EC, extending that obligation to processors, irrespective of the contract with the controller.

Articles 31 and 32 introduce an obligation to notify personal data breaches, building on the personal data breach notification in Article 4(3) of the e-privacy Directive 2002/58/EC.

3.4.4.3. Section 3 – Data protection impact assessment and prior authorisation

Article 33 introduces the obligation of controllers and processors to carry out a data protection impact assessment prior to risky processing operations.

Article 34 concerns the cases where authorisation by, and consultation of, the supervisory authority is mandatory prior to the processing, building on the concept of prior checking in Article 20 of Directive 95/46/EC.

3.4.4.4. Section 4 – Data protection officer

Article 35 introduces a mandatory data protection officer for the public sector, and, in the private sector, for large enterprises or where the core activities of the controller or processor consist of processing operations which require regular and systematic monitoring. This builds on Article 18(2) of Directive 95/46/EC which provided the possibility for Member States to introduce such requirement as a surrogate of a general notification requirement.

Article 36 sets out the position of the data protection officer.

Article 37 provides the core tasks of the data protection officer.

3.4.4.5. Section 5 – Codes of conduct and certification

Article 38 concerns codes of conduct, building on the concept of Article 27(1) of Directive 95/46/EC, clarifying the content of the codes and the procedures and providing for the empowerment of the Commission to decide on the general validity of codes of conduct.

Article 39 introduces the possibility to establish certification mechanisms and data protection seals and marks.

3.4.5. CHAPTER V - TRANSFER OF PERSONAL DATA TO THIRD COUNTRIES OR INTERNATIONAL ORGANISATIONS

Article 40 spells out, as a general principle, that the compliance with the obligations in that chapter are mandatory for any transfers of personal data to third countries or international organisations, including onward transfers.

Article 41 sets out the criteria, conditions and procedures for the adoption of an adequacy decision by the Commission, based on Article 25 of Directive 95/46/EC. The criteria which shall be taken into account for the Commission's assessment of an adequate or not adequate level of protection include expressly the rule of law, judicial redress and independent supervision. The article now confirms explicitly the possibility for the Commission to assess the level of protection afforded by a territory or a processing sector within a third country.

Article 42 requires for transfers to third countries, where no adequacy decision has been adopted by the Commission, to adduce appropriate safeguards, in particular standard data protection clauses, binding corporate rules and contractual clauses. The possibility of making use of Commission standard data protection clauses is based on Article 26(4) of Directive 95/46/EC. As a new component, such standard data protection clauses may now also be adopted by a supervisory authority and be declared generally valid by the Commission. Binding corporate rules are now specifically mentioned in the legal text. The option of contractual clauses gives certain flexibility to the controller or processor, but is subject to prior authorisation by supervisory authorities.

Article 43 describes in further detail the conditions for transfers by way of binding corporate rules, based on the current practices and requirements of supervisory authorities.

Article 44 spells out and clarifies the derogations for a data transfer, based on the existing provisions of Article 26 of Directive 95/46/EC. This applies in particular to data transfers required and necessary for the protection of important grounds of public interest, for example

in cases of international data transfers between competition authorities, tax or customs administrations, or between services competent for social security matters or for fisheries management. In addition, a data transfer may, under limited circumstances, be justified on a legitimate interest of the controller or processor, but only after having assessed and documented the circumstances of that transfer operation.

Article 45 explicitly provides for international co-operation mechanisms for the protection of personal data between the Commission and the supervisory authorities of third countries, in particular those considered offering an adequate level of protection, taking into account the Recommendation by the Organisation for Economic Co-operation and Development (OECD) on cross-border co-operation in the enforcement of laws protecting privacy of 12 June 2007.

3.4.6. CHAPTER VI - INDEPENDENT SUPERVISORY AUTHORITIES

3.4.6.1. Section 1 – Independent status

Article 46 obliges Member States to establish supervisory authorities, based on Article 28(1) of Directive 95/46/EC and enlarging the mission of the supervisory authorities to co-operation with each other and with the Commission.

Article 47 clarifies the conditions for the independence of supervisory authorities, implementing case law by the Court of Justice of the European Union[34], inspired also by Article 44 of Regulation (EC) No 45/2001[35].

Article 48 provides general conditions for the members of the supervisory authority, implementing the relevant case law[36] and inspired also by Article 42(2) to (6) of Regulation (EC) 45/2001.

Article 49 sets out rules on the establishment of the supervisory authority to be provided by the Member States by law.

Article 50 lays down professional secrecy of the members and staff of the supervisory authority and is based on Article 28(7) of Directive 95/46/EC.

3.4.6.2. Section 2 – Duties and powers

Article 51 sets out the competence of the supervisory authorities. The general rule, based on Article 28(6) of Directive 95/46/EC (competency on the territory of its own Member State), is complemented by the new competence as lead authority in case that a controller or processor is established in several Member States, to ensure unity of application ('one-stop shop'). Courts, when acting in their judicial authority, are exempted from the monitoring by the supervisory authority, but not from the application of the substantive rules on data protection.

Article 52 provides the duties of the supervisory authority, including hearing and investigating complaints and promoting the awareness of the public of risks, rules, safeguards and rights.

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34 Court of Justice of the EU, judgment of 9.3.2010, Commission / Germany, CaseC-518/07, ECR 2010 p. I-1885.

35 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 008 , 12/01/2001, p.1.

36 Op. cit, footnote 34.

Article 53 provides the powers of the supervisory authority, in parts building on Article 28(3) of Directive 95/46/EC and Article 47 of Regulation (EC) 45/2001, and adding some new elements, including the power to sanction administrative offences.

Article 54 obliges the supervisory authorities to draw up annual activity reports, based on Article 28(5) of Directive 95/46/EC.

3.4.7. CHAPTER VII - CO-OPERATION AND CONSISTENCY

3.4.7.1. Section 1 – Co-operation

Article 55 introduces explicit rules on mandatory mutual assistance, including consequences for non-compliance with the request of another supervisory, building on Article 28(6), second subparagraph, of Directive 95/46/EC.

Article 56 introduces rules on joint operations, inspired by Article 17 of Council Decision 2008/615/JHA[37], including a right of supervisory authorities to participate in such operations.

3.4.7.2. Section 2 – Consistency

Article 57 introduces a consistency mechanism for ensuring unity of application in relation to processing operations which may concern data subjects in several Member States.

Article 58 sets out the procedures and conditions for an opinion of the European Data Protection Board.

Article 59 concerns Commission opinions on matters dealt within the consistency mechanism, which may either reinforce the opinion of the European Data Protection Board or express a divergence with that opinion, and the draft measure of the supervisory authority. Where the matter has been raised by the European Data Protection Board under Article 58(3) it can be expected that the Commission will exercise its discretion and deliver an opinion whenever necessary.

Article 60 concerns Commission decisions requiring the competent authority to suspend its draft measure when this is necessary to ensure the correct application of this Regulation.

Article 61 provides for a possibility for the adoption of provisional measures, in an urgency procedure.

Article 62 sets out the requirements for Commission implementing acts under the consistency mechanism.

Article 63 provides the obligation to enforce measures of a supervisory authority in all Member States concerned, and sets out that the application of the consistency mechanism is a precondition for the legal validity and enforcement of the respective measure.

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37 Council Decision 2008/615/JHA of 23 June 2008 on the stepping up of cross-border cooperation, particularly in combating terrorism and cross-border crime, OJ L 210, 6.8.2008, p. 1.

3.4.7.3. Section 3 – European Data Protection Board

Article 64 establishes the European Data Protection Board, consisting of the heads of the supervisory authority of each Member State and of the European Data Protection Supervisor. The European Data Protection Board replaces the Working Party on the Protection of Individuals with regard to the Processing of Personal Data set up under Article 29 of Directive 95/46/EC. It is clarified that the Commission is not a member of the European Data Protection Board, but has the right to participate in the activities and to be represented.

Article 65 underlines and clarifies the independence of the European Data Protection Board.

Article 66 describes the tasks of the European Data Protection Board, based on Article 30(1) of Directive 95/46/EC, and provides for additional elements, reflecting the increased scope of activities of the European Data Protection Board, within the Union and beyond. In order to be able to react in urgent situations, it provides the Commission with the possibility to ask for an opinion within a specific time-limit.

Article 67 requires the European Data Protection Board to report annually on its activities, building on Article 30(6) of Directive 95/46/EC.

Article 68 sets out the European Data Protection Board's decision making procedures, including the obligation to adopt rules of procedure which should extend also to operational arrangements.

Article 69 contains the provisions on the chair and on the deputy chairs of the European Data Protection Board.

Article 70 sets out the tasks of the chair.

Article 71 sets out that the secretariat of the European Data Protection Board shall be provided by the European Data Protection Supervisor, and specifies the tasks of the secretariat.

Article 72 provides for rules on the confidentiality.

3.4.8. CHAPTER VIII - REMEDIES, LIABILITY AND SANCTIONS

Article 73 provides the right of any data subject to lodge a complaint with a supervisory authority, based on Article 28(4) of Directive 95/46/EC. It specifies also the bodies, organisations or associations which may lodge a complaint on behalf of the data subject or, in case of a personal data breach, independently of a data subject's complaint.

Article 74 concerns the right of judicial remedy against a supervisory authority. It builds on the general provision of Article 28(3) of Directive 95/46/EC. It provides specifically a judicial remedy obliging the supervisory authority to act on a complaint, and clarifies the competence of the courts of the Member State where the supervisory authority is established. It provides also the possibility that the supervisory authority of the Member State in which the data subject is residing, may bring on behalf of the data subject proceedings before the courts of another Member State where the competent supervisory authority is established.

Article 75 concerns the right to a judicial remedy against a controller or processor, building on Article 22 of Directive 95/46/EC, and providing a choice to go to court in the Member

State where the defendant is established or where the data subject is residing. Where proceedings concerning the same matter are pending in the consistency mechanism, the court may suspend its proceedings, except in case of urgency.

Article 76 lays down common rules for court proceedings, including the rights of bodies, organisations or associations to represent data subjects before the courts, the right of supervisory authorities to engage in legal proceedings and the information of the courts on parallel proceedings in another Member State, and the possibility for the courts to suspend in such case the proceedings.[38] There is an obligation on Member States to ensure rapid court actions.[39]

Article 77 sets out the right to compensation and liability. It builds on Article 23 of Directive 95/46/EC, extends this right to damages caused by processors and clarifies the liability of joint controllers and joint processors.

Article 78 obliges Member States to lay down rules on penalties, to sanction infringements of the Regulation, and to ensure their implementation.

Article 79 obliges each supervisory authority to sanction the administrative offences listed in the catalogues set out in this provision, imposing fines up to maximum amounts, with due regard to circumstances of each individual case.

3.4.9. CHAPTER IX - PROVISIONS RELATING TO SPECIFIC DATA PROCESSING SITUATIONS

Article 80 obliges Member States to adopt exemptions and derogations from specific provisions of the Regulation where necessary to reconcile the right to the protection of personal data with the right of freedom of expression. It is based on Article 9 of Directive 95/46/EC, as interpreted by the Court of Justice of the EU.[40]

Article 81 obliges Member States, further to the conditions for special categories of data, to ensure specific safeguards for processing for health purposes.

Article 82 provides an empowerment for Member States to adopt specific laws for processing personal data in the employment context.

Article 83 sets out specific conditions for processing personal data for historical, statistical and scientific research purposes.

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38 Building on Article 5(1) of Council Framework Decision 2009/948/JHA of 30 November 2009 on prevention and settlement of conflicts of exercise of jurisdiction in criminal proceedings, OJ L 328, 15/12/2009, p. 42; and Article 13(1) of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ L 1, 04.01.2003, p.1.

39 Building on Article 18(1) of 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.

40 Cf. for the interpretation, e.g. Court of Justice of the EU, judgment of 16 December 2008, Satakunnan Markkinapörssi and Satamedia (C-73/07, ECR 2008 p. I-9831).

Article 84 empowers Member States to adopt specific rules on the access of supervisory authorities to personal data and to premises, where controllers are subject to obligations of secrecy.

Article 85 allows in the light of Article 17 of the Treaty on the Functioning of the European Union for the continuous application of existing comprehensive data protection rules of churches if brought in line with this Regulation.

3.4.10. CHAPTER X - DELEGATED ACTS AND IMPLEMENTING ACTS

Article 86 contains the standard provisions for the exercise of the delegations in line with Article 290 TFEU. This allows the legislator to delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of a legislative act (quasi-legislative acts).

Article 87 contains the provision for the Committee procedure needed for conferring implementing powers on the Commission in the cases where in accordance with Article 291 TFEU uniform conditions for implementing legally binding acts of the Union are needed. The examination procedure applies.

3.4.11. CHAPTER XI - FINAL PROVISIONS

Article 88 repeals Directive 95/46/EC.

Article 89 clarifies the relationship to, and amends, the e-privacy Directive 2002/58/EC.

Article 90 obliges the Commission to evaluate the Regulation and submit related reports.

Article 91 sets out the date of the entry into force of the Regulation and a transitional phase as regards the date of its application.

4. BUDGETARY IMPLICATION

The specific budgetary implications of the proposal relate to the tasks allocated to the European Data Protection Supervisor as specified in the legislative financial statements accompanying this proposal. These implications require reprogramming of Heading 5 of the Financial Perspective.

The proposal has no implications on operational expenditure.

The legislative financial statement accompanying this proposal for a Regulation covers the budgetary impacts for the Regulation itself and for the Directive on police and justice data protection.

2012/0011 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of individuals with regard to the processing of personal data and on the free movement of such data (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(2) and Article 114(1) 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[41],

After consulting the European Data Protection Supervisor[42],

Acting in accordance with the ordinary legislative procedure,

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 and Article 16(1) of the Treaty lay down that everyone has the right to the protection of personal data concerning him or her.

(2) The processing of personal data is designed to serve man; the principles and rules on the protection of individuals with regard to the processing of their personal data should, whatever the nationality or residence of natural persons, respect their fundamental rights and freedoms, notably their right to the protection of personal data. It should contribute to the accomplishment of an area of freedom, security and justice and of an economic union, to economic and social progress, the strengthening and the convergence of the economies within the internal market, and the well-being of individuals.

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41 OJ C , , p. .
42 OJ C , , p. .

(3) 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[43] seeks to harmonise the protection of fundamental rights and freedoms of natural persons in respect of processing activities and to guarantee the free flow of personal data between Member States.

(4) The economic and social integration resulting from the functioning of the internal market has led to a substantial increase in cross-border flows. The exchange of data between economic and social, public and private actors across the Union increased. National authorities in the Member States are being called upon by Union law to co-operate 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.

(5) Rapid technological developments and globalisation have brought new challenges for the protection of personal data. The scale of data sharing and collecting has increased spectacularly. Technology allows both private companies and public authorities to make use of personal data on an unprecedented scale in order to pursue their activities. Individuals increasingly make personal information available publicly and globally. Technology has transformed both the economy and social life, and requires to further facilitate the free flow of data within the Union and the transfer to third countries and international organisations, while ensuring an high level of the protection of personal data.

(6) These developments require building a strong and more coherent data protection framework in the Union, backed by strong enforcement, given the importance to create the trust that will allow the digital economy to develop across the internal market. Individuals should have control of their own personal data and legal and practical certainty for individuals, economic operators and public authorities should be reinforced.

(7) The objectives and principles of Directive 95/46/EC remain sound, but it has not prevented fragmentation in the way data protection is implemented across the Union, legal uncertainty and a widespread public perception that there are significant risks for the protection of individuals associated notably with online activity. Differences in the level of protection of the rights and freedoms of individuals, notably to the right to the protection of personal data, with regard to the processing of personal data afforded in the Member States may prevent the free flow of personal data throughout the Union. These differences may therefore constitute an obstacle to the pursuit of economic activities at the level of the Union, distort competition and impede authorities in the discharge of their responsibilities under Union law. This difference in levels of protection is due to the existence of differences in the implementation and application of Directive 95/46/EC.

(8) In order to ensure consistent and high level of protection of individuals and to remove the obstacles to flows of personal data, the level of protection of the rights and freedoms of individuals with regard to the processing of such data should be equivalent in all Member States. Consistent and homogenous application of the rules

[43] OJ L 281, 23.11.1995, p. 31.

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.

(9) Effective protection of personal data throughout the Union requires strengthening and detailing the rights of data subjects and the obligations of those who process and determine the processing of personal data, but also equivalent powers for monitoring and ensuring compliance with the rules for the protection of personal data and equivalent sanctions for offenders in the Member States.

(10) Article 16(2) of the Treaty mandates the European Parliament and the Council to lay down the rules relating to the protection of individuals with regard to the processing of personal data and the rules relating to the free movement of personal data.

(11) In order to ensure a consistent level of protection for individuals throughout the Union and to prevent divergences hampering the free movement of 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 individuals 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 co-operation by the supervisory authorities of different Member States. To take account of the specific situation of micro, small and medium-sized enterprises, this Regulation includes a number of derogations. In addition, the Union institutions and bodies, 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 upon Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises.

(12) The protection afforded by this Regulation concerns natural persons, whatever their nationality or place of residence, in relation to the processing of personal data. With regard to the processing of data which concern 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, the protection of this Regulation should not be claimed by any person. This should also apply where the name of the legal person contains the names of one or more natural persons.

(13) The protection of individuals should be technologically neutral and not depend on the techniques used; otherwise this would create a serious risk of circumvention. The protection of individuals should apply to processing of personal data by automated means as well as to manual processing, if the 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.

(14) This Regulation does not address issues of protection of fundamental rights and freedoms or the free flow of data related to activities which fall outside the scope of Union law, nor does it cover the processing of personal data by the Union institutions,

bodies, offices and agencies, which are subject to Regulation (EC) No 45/2001[44], or 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.

(15) This Regulation should not apply to processing of personal data by a natural person, which are exclusively personal or domestic, such as correspondence and the holding of addresses, and without any gainful interest and thus without any connection with a professional or commercial activity. The exemption should also not apply to controllers or processors which provide the means for processing personal data for such personal or domestic activities.

(16) The protection of individuals 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, is subject of a specific legal instrument at Union level. Therefore, this Regulation should not apply to the processing activities for those purposes. However, data processed by public authorities under this Regulation when used for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties should be governed by the more specific legal instrument at Union level (Directive XX/YYY).

(17) This Regulation should be without prejudice to the application of Directive 2000/31/EC, in particular of the liability rules of intermediary service providers in Articles 12 to 15 of that Directive.

(18) This Regulation allows the principle of public access to official documents to be taken into account when applying the provisions set out in this Regulation.

(19) 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 or not. Establishment implies the effective and real exercise of activity through stable arrangements. The legal form of such arrangements, whether through a branch or a subsidiary with a legal personality, is not the determining factor in this respect.

(20) In order to ensure that individuals are not deprived of the protection to which they are entitled under this Regulation, the processing of personal data of data subjects residing in the Union by a controller not established in the Union should be subject to this Regulation where the processing activities are related to the offering of goods or services to such data subjects, or to the monitoring of the behaviour of such data subjects.

(21) In order to determine whether a processing activity can be considered to 'monitor the behaviour' of data subjects, it should be ascertained whether individuals are tracked on the internet with data processing techniques which consist of applying a 'profile' to an individual, particularly in order to take decisions concerning her or him or for analysing or predicting her or his personal preferences, behaviours and attitudes.

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[44] OJ L 8, 12.1.2001, p. 1.

(22) Where the national law of a Member State 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.

(23) The principles of protection should apply to any information concerning an identified or identifiable person. To determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the individual. The principles of data protection should not apply to data rendered anonymous in such a way that the data subject is no longer identifiable.

(24) When using online services, individuals may be associated with online identifiers provided by their devices, applications, tools and protocols, such as Internet Protocol addresses or cookie identifiers. This may leave traces which, combined with unique identifiers and other information received by the servers, may be used to create profiles of the individuals and identify them. It follows that identification numbers, location data, online identifiers or other specific factors as such need not necessarily be considered as personal data in all circumstances.

(25) Consent should be given explicitly by any appropriate method enabling a freely given specific and informed indication of the data subject's wishes, either by a statement or by a clear affirmative action by the data subject, ensuring that individuals are aware that they give their consent to the processing of personal data, including by ticking a box when visiting an Internet website or by any other statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of their personal data. Silence or inactivity should therefore not constitute consent. Consent should cover all processing activities carried out for the same purpose or purposes. If the data subject's consent is to be given following an electronic request, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided.

(26) Personal data relating to health should include in particular all data pertaining to the health status of a data subject; information about the registration of the individual for the provision of health services; information about payments or eligibility for healthcare with respect to the individual; a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes; any information about the individual collected in the course of the provision of health services to the individual; information derived from the testing or examination of a body part or bodily substance, including biological samples; identification of a person as provider of healthcare to the individual; or any information on e.g. a disease, disability, disease risk, medical history, clinical treatment, or the actual physiological or biomedical state of the data subject independent of its source, such as e.g. from a physician or other health professional, a hospital, a medical device, or an in vitro diagnostic test.

(27) 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, conditions and means of processing through stable arrangements. This criterion should not depend whether the processing of personal data is actually 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 such main establishment and are therefore

no determining criteria for a main establishment. The main establishment of the processor should be the place of its central administration in the Union.

(28) A group of undertakings should cover a controlling undertaking and its controlled undertakings, whereby the controlling undertaking should be the undertaking which can exercise 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.

(29) Children deserve specific protection of their personal data, as they may be less aware of risks, consequences, safeguards and their rights in relation to the processing of personal data. To determine when an individual is a child, this Regulation should take over the definition laid down by the UN Convention on the Rights of the Child.

(30) Any processing of personal data should be lawful, fair and transparent in relation to the individuals concerned. In particular, the specific purposes for which the data are processed should be explicit and legitimate and determined at the time of the collection of the data. The data should be adequate, relevant and limited to the minimum necessary for the purposes for which the data are processed; this requires in particular ensuring that the data collected are not excessive and that the period for which the data are stored is limited to a strict minimum. Personal data should only be processed if the purpose of the processing could not be fulfilled by other means. Every reasonable step should be taken to ensure that personal data which are inaccurate are rectified or deleted. In order to ensure that the data are not kept longer than necessary, time limits should be established by the controller for erasure or for a periodic review.

(31) In order for processing to be lawful, personal data should be processed on the basis of the consent of the person 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.

(32) Where processing is based on the data subject's consent, the controller should have the burden of proving that the data subject has given the 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 that and to what extent consent is given.

(33) In order to ensure free consent, it should be clarified that consent does not provide a valid legal ground where the individual has no genuine and free choice and is subsequently not able to refuse or withdraw consent without detriment.

(34) Consent should not provide a valid legal ground for the processing of personal data, where there is a clear imbalance between the data subject and the controller. This is especially the case where the data subject is in a situation of dependence from the controller, among others, where personal data are processed by the employer of employees' personal data in the employment context. Where the controller is a public authority, there would be an imbalance only in the specific data processing operations where the public authority can impose an obligation by virtue of its relevant public powers and the consent cannot be deemed as freely given, taking into account the interest of the data subject.

(35) Processing should be lawful where it is necessary in the context of a contract or the intended entering into a contract.

(36) Where processing is carried out in compliance with a legal obligation to which the controller is subject or where processing is necessary for the performance of a task carried out in the public interest or in the exercise of an official authority, the processing should have a legal basis in Union law, or in a Member State law which meets the requirements of the Charter of Fundamental Rights of the European Union for any limitation of the rights and freedoms. It is also for Union or national 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 administration or another natural or legal person governed by public law, or by private law such as a professional association.

(37) The processing of personal data should equally be regarded as lawful where it is necessary to protect an interest which is essential for the data subject's life.

(38) The legitimate interests of a controller may provide a legal basis for processing, provided that the interests or the fundamental rights and freedoms of the data subject are not overriding. This would need careful assessment in particular where the data subject is a child, given that children deserve specific protection. The data subject should have the right to object the processing, on grounds relating to their particular situation and free of charge. To ensure transparency, the controller should be obliged to explicitly inform the data subject on the legitimate interests pursued and on the right to object, and also be obliged to document these legitimate interests. Given that it is for the legislator to provide by law the legal basis for public authorities to process data, this legal ground should not apply for the processing by public authorities in the performance of their tasks.

(39) The processing of data to the extent strictly necessary 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 data, and the security of the related services offered by, or accessible via, these networks and systems, by public authorities, Computer Emergency Response Teams – CERTs, Computer Security Incident Response Teams – CSIRTs, providers of electronic communications networks and services and by providers of security technologies and services, constitutes a legitimate interest of the concerned data controller. 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.

(40) The processing of personal data for other purposes should be only allowed where the processing is compatible with those purposes for which the data have been initially collected, in particular where the processing is necessary for historical, statistical or scientific research purposes. Where the other purpose is not compatible with the initial one for which the data are collected, the controller should obtain the consent of the data subject for this other purpose or should base the processing on another legitimate ground for lawful processing, in particular where provided by Union law or the law of the Member State to which the controller is subject. In any case, the application of the

principles set out by this Regulation and in particular the information of the data subject on those other purposes should be ensured.

(41) Personal data which are, by their nature, particularly sensitive and vulnerable in relation to fundamental rights or privacy, deserve specific protection. Such data should not be processed, unless the data subject gives his explicit consent. However, derogations from this prohibition should be explicitly provided for 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.

(42) Derogating from the prohibition on processing sensitive categories of data should also be allowed if done by a law, and subject to suitable safeguards, so as to protect personal data and other fundamental rights, where grounds of public interest so justify and in particular for health purposes, including public health and social protection 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 historical, statistical and scientific research purposes.

(43) Moreover, the processing of personal data by official authorities for achieving aims, laid down in constitutional law or international public law, of officially recognised religious associations is carried out on grounds of public interest.

(44) Where in the course of electoral activities, the operation of the democratic system requires in a Member State that political parties compile 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.

(45) If the 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. In case of a request for access, the controller should be entitled to ask the data subject for further information to enable the data controller to locate the personal data which that person seeks.

(46) The principle of transparency requires that any information addressed to the public or to the data subject should be easily accessible and easy to understand, and that clear and plain language is used. This is in particular relevant where in situations, such as online advertising, the proliferation of actors and the technological complexity of practice makes it difficult for the data subject to know and understand if personal data relating to them are being collected, by whom and for what purpose. Given that children deserve specific protection, any information and communication, where processing is addressed specifically to a child, should be in such a clear and plain language that the child can easily understand.

(47) Modalities should be provided for facilitating the data subject's exercise of their rights provided by this Regulation, including mechanisms to request, free of charge, in particular access to data, rectification, erasure and to exercise the right to object. The controller should be obliged to respond to requests of the data subject within a fixed deadline and give reasons, in case he does not comply with the data subject's request.

(48) The principles of fair and transparent processing require that the data subject should be informed in particular of the existence of the processing operation and its purposes, how long the data will be stored, on the existence of the right of access, rectification or erasure and on the right to lodge a complaint. Where the data are collected from the data subject, the data subject should also be informed whether they are obliged to provide the data and of the consequences, in cases they do not provide such data.

(49) The information in relation to the processing of personal data relating to the data subject should be given to them at the time of collection, or, where the data are not collected from the data subject, within a reasonable period, depending on the circumstances of the case. Where data can be legitimately disclosed to another recipient, the data subject should be informed when the data are first disclosed to the recipient.

(50) However, it is not necessary to impose this obligation where the data subject already disposes of this information, or where the recording or disclosure of the data is expressly laid down by law, or where the provision of information to the data subject proves impossible or would involve disproportionate efforts. The latter could be particularly the case where processing is for historical, statistical or scientific research purposes; in this regard, the number of data subjects, the age of the data, and any compensatory measures adopted may be taken into consideration.

(51) Any person should have the right of access to data which has been collected concerning them, and to exercise this right easily, in order to be aware and verify the lawfulness of the processing. Every data subject should therefore have the right to know and obtain communication in particular for what purposes the data are processed, for what period, which recipients receive the data, what is the logic of the data that are undergoing the processing and what might be, at least when based on profiling, the consequences of such processing. This right should not adversely affect the rights and freedoms of others, including trade secrets or intellectual property and in particular the copyright protecting the software. However, the result of these considerations should not be that all information is refused to the data subject.

(52) The controller should use all reasonable measures to verify the identity of a data subject that requests access, in particular in the context of online services and online identifiers. A controller should not retain personal data for the unique purpose of being able to react to potential requests.

(53) Any person should have the right to have personal data concerning them rectified and a 'right to be forgotten' where the retention of such data is not in compliance with this Regulation. In particular, data subjects should have the right that their personal data are erased and no longer processed, where the data are no longer necessary in relation to the purposes for which the data are collected or otherwise processed, where data subjects have withdrawn their consent for processing or where they object to the processing of personal data concerning them or where the processing of their personal data otherwise does not comply with this Regulation. This right is particularly relevant, when the data subject has given their consent as a child, when not being fully aware of the risks involved by the processing, and later wants to remove such personal data especially on the Internet. However, the further retention of the data should be allowed where it is necessary for historical, statistical and scientific research purposes, for reasons of public interest in the area of public health, for exercising the right of

freedom of expression, when required by law or where there is a reason to restrict the processing of the data instead of erasing them.

(54) 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 third parties which are processing such data that a data subject requests them to erase any links to, or copies or replications of that personal data. To ensure this information, the controller should take all reasonable steps, including technical measures, in relation to data for the publication of which the controller is responsible. In relation to a third party publication of personal data, the controller should be considered responsible for the publication, where the controller has authorised the publication by the third party.

(55) To further strengthen the control over their own data and their right of access, data subjects should have the right, where personal data are processed by electronic means and in a structured and commonly used format, to obtain a copy of the data concerning them also in commonly used electronic format. The data subject should also be allowed to transmit those data, which they have provided, from one automated application, such as a social network, into another one. This should apply where the data subject provided the data to the automated processing system, based on their consent or in the performance of a contract.

(56) In cases where personal data might lawfully be processed to protect the vital interests of the data subject, or on grounds of public interest, official authority or the legitimate interests of a controller, any data subject should nevertheless be entitled to object to the processing of any data relating to them. The burden of proof should be on the controller to demonstrate that their legitimate interests may override the interests or the fundamental rights and freedoms of the data subject.

(57) Where personal data are processed for the purposes of direct marketing, the data subject should have the right to object to such processing free of charge and in a manner that can be easily and effectively invoked..

(58) Every natural person should have the right not to be subject to a measure which is based on profiling by means of automated processing. However, such measure should be allowed when expressly authorised by law, carried out in the course of entering or performance of a contract, or when the data subject has given his consent. In any case, such processing should be subject to suitable safeguards, including specific information of the data subject and the right to obtain human intervention and that such measure should not concern a child.

(59) Restrictions on specific principles and on the rights of information, access, rectification and erasure or on the right to data portability, the right to object, measures based on profiling, as well as on the communication of a personal data breach to a data subject and on 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 man made disasters, the prevention, investigation and prosecution of criminal offences or of breaches of ethics for regulated professions, other public interests of the Union or of a Member State, in particular an important economic or financial interest of the Union or of a Member State, or the protection of the data

subject or the rights and freedoms of others. Those restrictions should be in compliance with requirements set out by the Charter of Fundamental Rights of the European Union and by the European Convention for the Protection of Human Rights and Fundamental Freedoms.

(60) Comprehensive 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 ensure and be obliged to demonstrate the compliance of each processing operation with this Regulation.

(61) The protection of the rights and freedoms of data subjects with regard to the processing of personal data require that appropriate technical and organisational measures are taken, both at the time of the design of the processing and at the time of the processing itself, to ensure that the requirements of this Regulation are met. In order to ensure and demonstrate compliance with this Regulation, the controller should adopt internal policies and implement appropriate measures, which meet in particular the principles of data protection by design and data protection by default.

(62) The protection of the rights and freedoms of data subjects as well as the responsibility and liability of controllers and processor, also in relation to the monitoring by and measures of supervisory authorities, requires a clear attribution of the responsibilities under this Regulation, including where a controller determines the purposes, conditions and means of the processing jointly with other controllers or where a processing operation is carried out on behalf of a controller.

(63) Where a controller not established in the Union is processing personal data of data subjects residing in the Union whose processing activities are related to the offering of goods or services to such data subjects, or to the monitoring their behaviour, the controller should designate a representative, unless the controller is established in a third country ensuring an adequate level of protection, or the controller is a small or medium sized enterprise or a public authority or body or where the controller is only occasionally offering goods or services to such data subjects. The representative should act on behalf of the controller and may be addressed by any supervisory authority.

(64) In order to determine whether a controller is only occasionally offering goods and services to data subjects residing in the Union, it should be ascertained whether it is apparent from the controller's overall activities that the offering of goods and services to such data subjects is ancillary to those main activities.

(65) In order to demonstrate compliance with this Regulation, the controller or processor should document each processing operation. Each controller and processor should be obliged to co-operate with the supervisory authority and make this documentation, on request, available to it, so that it might serve for monitoring those processing operations.

(66) In order to maintain security and to prevent processing in breach of this Regulation, the controller or processor should evaluate the risks inherent to the processing and implement measures to mitigate those risks. These measures should ensure an appropriate level of security, taking into account the state of the art and the costs of their implementation in relation to the risks and the nature of the personal data to be

protected. When establishing technical standards and organisational measures to ensure security of processing, the Commission should promote technological neutrality, interoperability and innovation, and, where appropriate, cooperate with third countries.

(67) A personal data breach may, if not addressed in an adequate and timely manner, result in substantial economic loss and social harm, including identity fraud, to the individual concerned. Therefore, as soon as the controller becomes aware that such a breach has occurred, the controller should notify the breach to the supervisory authority without undue delay and, where feasible, within 24 hours. Where this cannot achieved within 24 hours, an explanation of the reasons for the delay should accompany the notification. The individuals whose personal data could be adversely affected by the breach should be notified without undue delay in order to allow them to take the necessary precautions. A breach should be considered as adversely affecting the personal data or privacy of a data subject where it could result in, for example, identity theft or fraud, physical harm, significant humiliation or damage to reputation. The notification should describe the nature of the personal data breach as well as recommendations as well as recommendations for the individual concerned to mitigate potential adverse effects. Notifications to data subjects should be made as soon as reasonably feasible, and in close cooperation with the supervisory authority and respecting guidance provided by it or other relevant authorities (e.g. law enforcement authorities). For example, the chance for data subjects to mitigate an immediate risk of harm would call for a prompt notification of data subjects whereas the need to implement appropriate measures against continuing or similar data breaches may justify a longer delay.

(68) In order to determine whether a personal data breach is notified to the supervisory authority and to the data subject without undue delay, it should be ascertained whether the controller has implemented and applied appropriate technological protection and organisational measures to establish immediately whether a personal data breach has taken place and to inform promptly the supervisory authority and the data subject, before a damage to personal and economic interests occurs, taking into account in particular the nature and gravity of the personal data breach and its consequences and adverse effects for the data subject.

(69) 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 the 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 in cases where early disclosure could unnecessarily hamper the investigation of the circumstances of a breach.

(70) Directive 95/46/EC provided for a general obligation to notify processing of personal data to the supervisory authorities. While this obligation produces administrative and financial burdens, it did not in all cases contribute to improving the protection of personal data. Therefore such indiscriminate general notification obligation should be abolished, and replaced by effective procedures and mechanism which focus instead on those processing operations which are likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes. In

such cases, a data protection impact assessment should be carried out by the controller or processor prior to the processing, which should include in particular the envisaged measures, safeguards and mechanisms for ensuring the protection of personal data and for demonstrating the compliance with this Regulation.

(71) This should in particular apply to newly established large scale filing systems, which aim at processing a considerable amount of personal data at regional, national or supranational level and which could affect a large number of data subjects.

(72) There are circumstances under which it may be sensible and economic that the subject of a data protection impact assessment should 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.

(73) Data protection impact assessments should be carried out by a public authority or public body if such an assessment has not already been made in the context of the adoption of the national 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.

(74) Where a data protection impact assessment indicates that processing operations involve a high degree of specific risks to the rights and freedoms of data subjects, such as excluding individuals from their right, or by the use of specific new technologies, the supervisory authority should be consulted, prior to the start of operations, on a risky processing which might not be in compliance with this Regulation, and to make proposals to remedy such situation. Such consultation should equally take place in the course of the preparation either of a measure by the national parliament or of a measure based on such legislative measure which defines the nature of the processing and lays down appropriate safeguards.

(75) Where the processing is carried out in the public sector or where, in the private sector, processing is carried out by a large enterprise, or where its core activities, regardless of the size of the enterprise, involve processing operations which require regular and systematic monitoring, a person should assist the controller or processor to monitor internal compliance with this Regulation. Such data protection officers, whether or not an employee of the controller, should be in a position to perform their duties and tasks independently.

(76) Associations or other bodies representing categories of controllers 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.

(77) In order to enhance transparency and compliance with this Regulation, the establishment of certification mechanisms, data protection seals and marks should be encouraged, allowing data subjects to quickly assess the level of data protection of relevant products and services.

(78) Cross-border flows of personal data are necessary for the expansion of international trade and international co-operation. The increase in these flows has raised new challenges and concerns with respect to the protection of personal data. However, when personal data are transferred from the Union to third countries or to international organisations, the level of protection of individuals guaranteed in the Union by this Regulation should not be undermined. In any event, transfers to third countries may only be carried out in full compliance with this Regulation.

(79) 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.

(80) The Commission may decide with effect for the entire Union that certain third countries, or a territory or a processing sector within a third country, or an international organisation, offer an adequate level of data protection, thus providing legal certainty and uniformity throughout the Union as regards the third countries or international organisations which are considered to provide such level of protection. In these cases, transfers of personal data to these countries may take place without needing to obtain any further authorisation.

(81) 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, take into account how a given third country respects the rule of law, access to justice as well as international human rights norms and standards.

(82) The Commission may equally recognise that a third country, or a territory or a processing sector within a third country, or an international organisation offers no adequate level of data protection. Consequently the transfer of personal data to that third country should be prohibited. In that case, provision should be made for consultations between the Commission and such third countries or international organisations.

(83) 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, or other suitable and proportionate measures justified in the light of all the circumstances surrounding a data transfer operation or set of data transfer operations and where authorised by a supervisory authority.

(84) The possibility for the controller or processor to use standard data protection clauses adopted by the Commission or by a supervisory authority should neither prevent the possibility for controllers or processors to include the standard data protection clauses in a wider contract nor to add other clauses as long as 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.

(85) A corporate group should be able to make use of approved binding corporate rules for its international transfers from the Union to organisations within the same corporate group of undertakings, as long as such corporate rules include essential principles and enforceable rights to ensure appropriate safeguards for transfers or categories of transfers of personal data.

(86) Provisions should be made for the possibility for transfers in certain circumstances where the data subject has given his consent, where the transfer is necessary in relation to a contract or a legal claim, 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 by law and intended for consultation by the public or persons having a legitimate interest. In this latter case such a transfer should not involve the entirety of the 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.

(87) These derogations should in particular apply to data transfers required and necessary for the protection of important grounds of public interest, for example in cases of international data transfers between competition authorities, tax or customs administrations, financial supervisory authorities, between services competent for social security matters, or to competent authorities for the prevention, investigation, detection and prosecution of criminal offences.

(88) Transfers which cannot be qualified as frequent or massive, could also be possible for the purposes of the legitimate interests pursued by the controller or the processor, when they have assessed all the circumstances surrounding the data transfer. For the purposes of processing for historical, statistical and scientific research purposes, the legitimate expectations of society for an increase of knowledge should be taken into consideration.

(89) 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 a guarantee that they will continue to benefit from the fundamental rights and safeguards as regards processing of their data in the Union once this data has been transferred.

(90) Some third countries enact laws, regulations and other legislative instruments which purport to directly regulate data processing activities of natural and legal persons under the jurisdiction of the Member States. The extraterritorial application of these laws, regulations and other legislative instruments may be in breach of international law and may impede the attainment of the protection of individuals guaranteed 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 inter alia be the case where the disclosure is necessary for an important ground of public interest recognised in Union law or in a Member State law to which the controller is subject. The conditions under which an important ground of public interest exists should be further specified by the Commission in a delegated act.

(91) When personal data moves across borders it may put at increased risk the ability of individuals 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 co-operation among data protection supervisory authorities to help them exchange information and carry out investigations with their international counterparts.

(92) The establishment of supervisory authorities in Member States, exercising their functions with complete independence, is an essential component of the protection of individuals with regard to the processing of their personal data. Member States may establish more than one supervisory authority, to reflect their constitutional, organisational and administrative structure.

(93) 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 co-operation with other supervisory authorities, the European Data Protection Board and the Commission.

(94) Each supervisory authority should be provided with the adequate financial and human resources, premises and infrastructure, which is necessary for the effective performance of their tasks, including for the tasks related to mutual assistance and co-operation with other supervisory authorities throughout the Union.

(95) The general conditions for the members of the supervisory authority should be laid down by law in each Member State and should in particular provide that those members should be either appointed by the parliament or the government of the Member State, and include rules on the personal qualification of the members and the position of those members.

(96) 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 co-operate with each other and the Commission.

(97) Where the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union takes place in more than one Member State, one single supervisory authority should be competent for monitoring the activities of the controller or processor throughout the Union and taking the related decisions, in order to increase the consistent application, provide legal certainty and reduce administrative burden for such controllers and processors.

(98) The competent authority, providing such one-stop shop, should be the supervisory authority of the Member State in which the controller or processor has its main establishment.

(99) While this Regulation applies also to the activities of national courts, 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 judges in the performance of their judicial tasks. However, this exemption should be strictly limited to genuine judicial activities in court cases and not apply to other activities where judges might be involved in, in accordance with national law.

(100) 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 duties and effective powers, including powers of investigation, legally binding intervention, decisions and sanctions, particularly in cases of complaints from individuals, and to engage in legal proceedings. Investigative powers of supervisory authorities as regards access to premises should be exercised in conformity with Union law and national law. This concerns in particular the requirement to obtain a prior judicial authorisation.

(101) Each supervisory authority should hear complaints lodged by any data subject and should investigate the matter. 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.

(102) 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 data subjects.

(103) The supervisory authorities should assist each other in performing their duties and provide mutual assistance, so as to ensure the consistent application and enforcement of this Regulation in the internal market.

(104) Each supervisory authority should have the right to participate in joint operations between supervisory authorities. The requested supervisory authority should be obliged to respond to the request in a defined time period.

(105) In order to ensure the consistent application of this Regulation throughout the Union, a consistency mechanism for co-operation between the supervisory authorities themselves and the Commission should be established. This mechanism should in particular apply where a supervisory authority intends to take a measure as regards processing operations that are related to the offering of goods or services to data subjects in several Member States, , or to the monitoring such data subjects, or that might substantially affect the free flow of personal data. It should also apply where any supervisory authority or the Commission requests that the matter should be dealt with in the consistency mechanism. This mechanism should be without prejudice to any measures that the Commission may take in the exercise of its powers under the Treaties.

(106) In application of the consistency mechanism, the European Data Protection Board should, within a determined period of time, issue an opinion, if a simple majority of its

members so decides or if so requested by any supervisory authority or the Commission.

(107) In order to ensure compliance with this Regulation, the Commission may adopt an opinion on this matter, or a decision, requiring the supervisory authority to suspend its draft measure.

(108) There may be an urgent need to act in order to protect the interests of data subjects, in particular when the danger exists that the enforcement of a right of a data subject could be considerably impeded. Therefore, a supervisory authority should be able to adopt provisional measures with a specified period of validity when applying the consistency mechanism.

(109) The application of this mechanism should be a condition for the legal validity and enforcement of the respective decision by a supervisory authority. In other cases of cross-border relevance, mutual assistance and joint investigations might be carried out between the concerned supervisory authorities on a bilateral or multilateral basis without triggering the consistency mechanism.

(110) At Union level, a European Data Protection Board should be set up. 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 a head of a supervisory authority of each Member State and of the European Data Protection Supervisor. The Commission should participate in its activities. The European Data Protection Board should contribute to the consistent application of this Regulation throughout the Union, including by advising the Commission and promoting co-operation of the supervisory authorities throughout the Union. The European Data Protection Board should act independently when exercising its tasks.

(111) Every data subject should have the right to lodge a complaint with a supervisory authority in any Member State and have the right to a judicial remedy if they consider that their rights under this Regulation are infringed or where the supervisory authority does not react on a complaint or does not act where such action is necessary to protect the rights of the data subject.

(112) Any body, organisation or association which aims to protects the rights and interests of data subjects in relation to the protection of their data and is constituted according to the law of a Member State should have the right to lodge a complaint with a supervisory authority or exercise the right to a judicial remedy on behalf of data subjects, or to lodge, independently of a data subject's complaint, an own complaint where it considers that a personal data breach has occurred.

(113) Each natural or legal person should have the right to a judicial remedy against decisions of a supervisory authority concerning them. Proceedings against a supervisory authority should be brought before the courts of the Member State, where the supervisory authority is established.

(114) In order to strengthen the judicial protection of the data subject in situations where the competent supervisory authority is established in another Member State than the one where the data subject is residing, the data subject may request any body, organisation or association aiming to protect the rights and interests of data subjects in relation to

the protection of their data to bring on the data subject's behalf proceedings against that supervisory authority to the competent court in the other Member State.

(115) In situations where the competent supervisory authority established in another Member State does not act or has taken insufficient measures in relation to a complaint, the data subject may request the supervisory authority in the Member State of his or her habitual residence to bring proceedings against that supervisory authority to the competent court in the other Member State. The requested supervisory authority may decide, subject to judicial review, whether it is appropriate to follow the request or not.

(116) 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 acting in the exercise of its public powers.

(117) Where there are indications that parallel proceedings are pending before the courts in different Member States, the courts should be obliged to contact each other. The courts should have the possibility to suspend a case where a parallel case is pending in another Member State. Member States should ensure that court actions, in order to be effective, should allow the rapid adoption of measures to remedy or prevent an infringement of this Regulation.

(118) Any damage which a person may suffer as a result of unlawful processing should be compensated by the controller or processor, who may be exempted from liability if they prove that they are not responsible for the damage, in particular where he establishes fault on the part of the data subject or in case of force majeure.

(119) Penalties should be imposed to any person, whether governed by private or public law, who fails to comply with this Regulation. Member States should ensure that the penalties should be effective, proportionate and dissuasive and should take all measures to implement the penalties.

(120) In order to strengthen and harmonise administrative sanctions against infringements of this Regulation, each supervisory authority should have the power to sanction administrative offences. This Regulation should indicate these offences and the upper limit for the related administrative fines, which should be fixed in each individual case proportionate to the specific situation, with due regard in particular to the nature, gravity and duration of the breach. The consistency mechanism may also be used to cover divergences in the application of administrative sanctions.

(121) The processing of personal data solely for journalistic purposes, or for the purposes of artistic or literary expression should qualify for exemption from the requirements of certain provisions of this Regulation in order to reconcile the right to the protection of personal data with the right to freedom of expression, and notably the right to receive and impart information, as guaranteed in particular by Article 11 of the Charter of Fundamental Rights of the European Union. This should apply in particular to processing of personal data in the audiovisual field and in news archives and press libraries. Therefore, Member States should adopt legislative measures, which should lay down exemptions and derogations which are necessary for the purpose of balancing these fundamental rights. Such exemptions and derogations should be

adopted by the Member States on general principles, on the rights of the data subject, on controller and processor, on the transfer of data to third countries or international organisations, on the independent supervisory authorities and on co-operation and consistency. This should not, however, lead Member States to lay down exemptions from the other provisions of this Regulation. 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. Therefore, Member States should classify activities as "journalistic" for the purpose of the exemptions and derogations to be laid down under this Regulation if the object of these activities is the disclosure to the public of information, opinions or ideas, irrespective of the medium which is used to transmit them. They should not be limited to media undertakings and may be undertaken for profit-making or for non-profit making purposes.

(122) The processing of personal data concerning health, as a special category of data which deserves higher protection, may often be justified by a number of legitimate reasons for the benefit of individuals and society as a whole, in particular in the context of ensuring continuity of cross-border healthcare. Therefore this Regulation should provide for harmonised conditions for the processing of personal data concerning health, subject to specific and suitable safeguards so as to protect the fundamental rights and the personal data of individuals. This includes the right for individuals to have access to their personal data concerning their health, for example the data in their medical records containing such information as diagnosis, examination results, assessments by treating physicians and any treatment or interventions provided.

(123) The processing of personal data concerning health may be necessary for reasons of public interest in the areas of public health, without consent of the data subject. In that context, 'public health' should be interpreted as defined in 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, meaning 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 personal 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, insurance and banking companies.

(124) The general principles on the protection of individuals with regard to the processing of personal data should also be applicable to the employment context. Therefore, in order to regulate the processing of employees' personal data in the employment context, Member States should be able, within the limits of this Regulation, to adopt by law specific rules for the processing of personal data in the employment sector.

(125) The processing of personal data for the purposes of historical, statistical or scientific research should, in order to be lawful, also respect other relevant legislation such as on clinical trials.

(126) Scientific research for the purposes of this Regulation should include fundamental research, applied research, and privately funded research and in addition should take

into account the Union's objective under Article 179(1) of the Treaty on the Functioning of the European Union of achieving a European Research Area.

(127) As regards the powers of the supervisory authorities to obtain from the controller or processor access personal data and access to its 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.

(128) This Regulation respects and does not prejudice the status under national law of churches and religious associations or communities in the Member States, as recognised in Article 17 of the Treaty on the Functioning of the European Union. As a consequence, where a church in a Member State applies, at the time of entry into force of this Regulation, comprehensive rules relating to the protection of individuals with regard to the processing of personal data, these existing rules should continue to apply if they are brought in line with this Regulation. Such churches and religious associations should be required to provide for the establishment of a completely independent supervisory authority.

(129) 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 of the Treaty on the Functioning of the European Union should be delegated to the Commission. In particular, delegated acts should be adopted in respect of lawfulness of processing; specifying the criteria and conditions in relation to the consent of a child; processing of special categories of data; specifying the criteria and conditions for manifestly excessive requests and fees for exercising the rights of the data subject; criteria and requirements for the information to the data subject and in relation to the right of access; the right to be forgotten and to erasure; measures based on profiling; criteria and requirements in relation to the responsibility of the controller and to data protection by design and by default; a processor; criteria and requirements for the documentation and the security of processing; criteria and requirements for establishing a personal data breach and for its notification to the supervisory authority, and on the circumstances where a personal data breach is likely to adversely affect the data subject; the criteria and conditions for processing operations requiring a data protection impact assessment; the criteria and requirements for determining a high degree of specific risks which require prior consultation; designation and tasks of the data protection officer; codes of conduct; criteria and requirements for certification mechanisms; criteria and requirements for transfers by way of binding corporate rules; transfer derogations; administrative sanctions; processing for health purposes; processing in the employment context and processing for historical, statistical and scientific research purposes. 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 Council.

(130) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission for: specifying standard forms in relation to the processing of personal data of a child; standard procedures and forms for exercising the rights of data subjects; standard forms for the information to

the data subject; standard forms and procedures in relation to the right of access; the right to data portability; standard forms in relation to the responsibility of the controller to data protection by design and by default and to the documentation; specific requirements for the security of processing; the standard format and the procedures for the notification of a personal data breach to the supervisory authority and the communication of a personal data breach to the data subject; standards and procedures for a data protection impact assessment; forms and procedures for prior authorisation and prior consultation; technical standards and mechanisms for certification; the adequate level of protection afforded by a third country or a territory or a processing sector within that third country or an international organisation; disclosures not authorized by Union law; mutual assistance; joint operations; decisions under the consistency mechanism. Those powers should be exercised in accordance with 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 the Member States of the Commission's exercise of implementing powers[45]. In this context, the Commission should consider specific measures for micro, small and medium-sized enterprises.

(131) The examination procedure should be used for the adoption of specifying standard forms in relation to the consent of a child; standard procedures and forms for exercising the rights of data subjects; standard forms for the information to the data subject; standard forms and procedures in relation to the right of access;, the right to data portability; standard forms in relation to the responsibility of the controller to data protection by design and by default and to the documentation; specific requirements for the security of processing; the standard format and the procedures for the notification of a personal data breach to the supervisory authority and the communication of a personal data breach to the data subject; standards and procedures for a data protection impact assessment; forms and procedures for prior authorisation and prior consultation; technical standards and mechanisms for certification; the adequate level of protection afforded by a third country or a territory or a processing sector within that third country or an international organisation; disclosures not authorized by Union law; mutual assistance; joint operations; decisions under the consistency mechanism, given that those acts are of general scope.

(132) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to a third country or a territory or a processing sector within that third country or an international organisation which does not ensure an adequate level of protection and relating to matters communicated by supervisory authorities under the consistency mechanism, imperative grounds of urgency so require.

(133) Since the objectives of this Regulation, namely to ensure an equivalent level of protection of individuals and the free flow of data throughout the Union, cannot be sufficiently achieved by the Member States and can therefore, 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

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[45] 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.

European Union. 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.

(134) Directive 95/46/EC should be repealed by this Regulation. However, Commission decisions adopted and authorisations by supervisory authorities based on Directive 95/46/EC should remain in force.

(135) This Regulation should apply to all matters concerning the protection of fundamental rights and freedom 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, including the obligations on the controller and the rights of individuals. In order to clarify the relationship between this Regulation and Directive 2002/58/EC, the latter Directive should be amended accordingly.

(136) As regards Iceland and Norway, this Regulation constitutes a development of provisions of the Schengen acquis to the extent that it applies to the processing of personal data by authorities involved in the implementation of that acquis, as provided for by the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis[46].

(137) As regards Switzerland, this Regulation constitutes a development of provisions of the Schengen acquis to the extent that it applies to the processing of personal data by authorities involved in the implementation of that acquis, as provided for by the Agreement between the European Union, the European Community and the Swiss Confederation concerning the association of the Swiss Confederation with the implementation, application and development of the Schengen acquis[47].

(138) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen acquis to the extent that it applies to the processing of personal data by authorities involved in the implementation of that acquis, as provided for by the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis[48].

(139) In view of the fact that, as underlined by the Court of Justice of the European Union, the right to the protection of personal data is not an absolute right, but must be considered in relation to its function in society and be balanced with other fundamental rights, in accordance with the principle of proportionality, this Regulation respects all fundamental rights and observes the principles recognised in the Charter of Fundamental Rights of the European Union as enshrined in the Treaties, notably the right to respect for private and family life, home and communications, the right to the protection of personal data, the freedom of thought, conscience and religion, the

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46 OJ L 176, 10.7.1999, p. 36.
47 OJ L 53, 27.2.2008, p. 52.
48 OJ L 160 of 18.6.2011, p. 19.

freedom of expression and information, the freedom to conduct a business, the right to an effective remedy and to a fair trial as well as cultural, religious and linguistic diversity.

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PROVISIONS

Article 1
Subject matter and objectives

1. This Regulation lays down rules relating to the protection of individuals with regard to the processing of personal data and rules relating to the free movement of personal data.

2. This Regulation protects the fundamental rights and freedoms of natural persons, and in particular their right to the protection of personal data.

3. The free movement of personal data within the Union shall neither be restricted nor prohibited for reasons connected with the protection of individuals with regard to the processing of personal data.

Article 2
Material scope

1. This Regulation applies to the processing of personal data wholly or partly by automated means, and to the processing other than by automated means of personal data which form part of a filing system or are intended to form part of a filing system.

2. This Regulation does not apply to the processing of personal data:

   (a) in the course of an activity which falls outside the scope of Union law, in particular concerning national security;

   (b) by the Union institutions, bodies, offices and agencies;

   (c) by the Member States when carrying out activities which fall within the scope of Chapter 2 of the Treaty on European Union;

   (d) by a natural person without any gainful interest in the course of its own exclusively personal or household activity;

   (e) by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties.

3. This Regulation shall be without prejudice to the application of Directive 2000/31/EC, in particular of the liability rules of intermediary service providers in Articles 12 to 15 of that Directive.

Article 3
Territorial scope

1. This Regulation applies to the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union.

2. This Regulation applies to the processing of personal data of data subjects residing in the Union by a controller not established in the Union, where the processing activities are related to:

   (a) the offering of goods or services to such data subjects in the Union; or

   (b) the monitoring of their behaviour.

3. This Regulation applies to the processing of personal data by a controller not established in the Union, but in a place where the national law of a Member State applies by virtue of public international law.

Article 4
Definitions

For the purposes of this Regulation:

(1) 'data subject' means an identified natural person or a natural person who can be identified, directly or indirectly, by means reasonably likely to be used by the controller or by any other natural or legal person, in particular by reference to an identification number, location data, online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person;

(2) 'personal data' means any information relating to a data subject;

(3) 'processing' means any operation or set of operations which is performed upon personal data or sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, erasure or destruction;

(4) 'filing system' means any structured set of personal data which are accessible according to specific criteria, whether centralized, decentralized or dispersed on a functional or geographical basis;

(5) 'controller' means the natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes, conditions and means of the processing of personal data; where the purposes, conditions and means of processing are determined by Union law or Member State law, the controller or

the specific criteria for his nomination may be designated by Union law or by Member State law;

(6) 'processor' means a natural or legal person, public authority, agency or any other body which processes personal data on behalf of the controller;

(7) 'recipient' means a natural or legal person, public authority, agency or any other body to which the personal data are disclosed;

(8) 'the data subject's consent' means any freely given specific, informed and explicit indication of his or her wishes by which the data subject, either by a statement or by a clear affirmative action, signifies agreement to personal data relating to them being processed;

(9) 'personal data breach' means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed;

(10) 'genetic data' means all data, of whatever type, concerning the characteristics of an individual which are inherited or acquired during early prenatal development;

(11) 'biometric data' means any data relating to the physical, physiological or behavioural characteristics of an individual which allow their unique identification, such as facial images, or dactyloscopic data;

(12) 'data concerning health' means any information which relates to the physical or mental health of an individual, or to the provision of health services to the individual;

(13) 'main establishment' means as regards the controller, the place of its establishment in the Union where the main decisions as to the purposes, conditions and means of the processing of personal data are taken; if no decisions as to the purposes, conditions and means of the processing of personal data are taken in the Union, the main establishment is the place where the main processing activities in the context of the activities of an establishment of a controller in the Union take place. As regards the processor, 'main establishment' means the place of its central administration in the Union;

(14) 'representative' means any natural or legal person established in the Union who, explicitly designated by the controller, acts and may be addressed by any supervisory authority and other bodies in the Union instead of the controller, with regard to the obligations of the controller under this Regulation;

(15) 'enterprise' means any entity engaged in an economic activity, irrespective of its legal form, thus including, in particular, natural and legal persons, partnerships or associations regularly engaged in an economic activity;

(16) 'group of undertakings' means a controlling undertaking and its controlled undertakings;

(17) 'binding corporate rules' means personal data protection policies which are adhered to by a controller or processor established on the territory of a Member State of the

Union for transfers or a set of transfers of personal data to a controller or processor in one or more third countries within a group of undertakings;

(18) 'child' means any person below the age of 18 years;

(19) 'supervisory authority' means a public authority which is established by a Member State in accordance with Article 46.

CHAPTER II
PRINCIPLES

Article 5
Principles relating to personal data processing

Personal data must be:

(a) processed lawfully, fairly and in a transparent manner in relation to the data subject;

(b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes;

(c) adequate, relevant, and limited to the minimum necessary in relation to the purposes for which they are processed; they shall only be processed if, and as long as, the purposes could not be fulfilled by processing information that does not involve personal data;

(d) accurate and kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay;

(e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the data will be processed solely for historical, statistical or scientific research purposes in accordance with the rules and conditions of Article 83 and if a periodic review is carried out to assess the necessity to continue the storage;

(f) processed under the responsibility and liability of the controller, who shall ensure and demonstrate for each processing operation the compliance with the provisions of this Regulation.

Article 6
Lawfulness of processing

1. Processing of personal data shall be lawful only if and to the extent that at least one of the following applies:

(a) the data subject has given consent to the processing of their personal data for one or more specific purposes;

(b) processing is necessary 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;

(c) processing is necessary for compliance with a legal obligation to which the controller is subject;

(d) processing is necessary in order to protect the vital interests of the data subject;

(e) 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;

(f) processing is necessary for the purposes of the legitimate interests pursued by a controller, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child. This shall not apply to processing carried out by public authorities in the performance of their tasks.

2. Processing of personal data which is necessary for the purposes of historical, statistical or scientific research shall be lawful subject to the conditions and safeguards referred to in Article 83.

3. The basis of the processing referred to in points (c) and (e) of paragraph 1 must be provided for in:

(a) Union law, or

(b) the law of the Member State to which the controller is subject.

The law of the Member State must meet an objective of public interest or must be necessary to protect the rights and freedoms of others, respect the essence of the right to the protection of personal data and be proportionate to the legitimate aim pursued.

4. Where the purpose of further processing is not compatible with the one for which the personal data have been collected, the processing must have a legal basis at least in one of the grounds referred to in points (a) to (e) of paragraph 1. This shall in particular apply to any change of terms and general conditions of a contract.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the conditions referred to in point (f) of paragraph 1 for various sectors and data processing situations, including as regards the processing of personal data related to a child.

Article 7

Conditions for consent

1. The controller shall bear the burden of proof for the data subject's consent to the processing of their personal data for specified purposes.

2. If the data subject's consent is to be given in the context of a written declaration which also concerns another matter, the requirement to give consent must be presented distinguishable in its appearance from this other matter.

3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal.

4. Consent shall not provide a legal basis for the processing, where there is a significant imbalance between the position of the data subject and the controller.

Article 8

Processing of personal data of a child

1. For the purposes of this Regulation, in relation to the offering of information society services directly to a child, the processing of personal data of a child below the age of 13 years shall only be lawful if and to the extent that consent is given or authorised by the child's parent or custodian. The controller shall make reasonable efforts to obtain verifiable consent, taking into consideration available technology.

2. Paragraph 1 shall not affect the general contract law of Member States such as the rules on the validity, formation or effect of a contract in relation to a child.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the methods to obtain verifiable consent referred to in paragraph 1. In doing so, the Commission shall consider specific measures for micro, small and medium-sized enterprises.

4. The Commission may lay down standard forms for specific methods to obtain verifiable consent referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

Article 9

Processing of special categories of personal data

1. The processing of personal data, revealing race or ethnic origin, political opinions, religion or beliefs, trade-union membership, and the processing of genetic data or data concerning health or sex life or criminal convictions or related security measures shall be prohibited.

2. Paragraph 1 shall not apply where:

(a) the data subject has given consent to the processing of those personal data, subject to the conditions laid down in Articles 7 and 8, except where Union law or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject; or

(b) processing is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller in the field of employment law in so far as it is authorised by Union law or Member State law providing for adequate safeguards; or

(c) processing is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving consent; or

(d) processing is carried out in the course of its legitimate activities with appropriate safeguards by a foundation, association or any other non-profit-seeking body with a political, philosophical, religious or trade-union aim and on condition that the processing relates solely to the members or to former members of the body or to persons who have regular contact with it in connection with its purposes and that the data are not disclosed outside that body without the consent of the data subjects; or

(e) the processing relates to personal data which are manifestly made public by the data subject; or

(f) processing is necessary for the establishment, exercise or defence of legal claims; or

(g) processing is necessary for the performance of a task carried out in the public interest, on the basis of Union law, or Member State law which shall provide for suitable measures to safeguard the data subject's legitimate interests; or

(h) processing of data concerning health is necessary for health purposes and subject to the conditions and safeguards referred to in Article 81; or

(i) processing is necessary for historical, statistical or scientific research purposes subject to the conditions and safeguards referred to in Article 83; or

(j) processing of data relating to criminal convictions or related security measures is carried out either under the control of official authority or when the processing is necessary for compliance with a legal or regulatory obligation to which a controller is subject, or for the performance of a task carried out for important public interest reasons, and in so far as authorised by Union law or Member State law providing for adequate safeguards. A complete register of criminal convictions shall be kept only under the control of official authority.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria, conditions and appropriate safeguards for the processing of the special categories of personal data referred to in paragraph 1 and the exemptions laid down in paragraph 2.

Article 10
Processing not allowing identification

If the data processed by a controller do not permit the controller to identify a natural person, the controller shall 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.

CHAPTER III
RIGHTS OF THE DATA SUBJECT

SECTION 1
TRANSPARENCY AND MODALITIES

Article 11
Transparent information and communication

1. The controller shall have transparent and easily accessible policies with regard to the processing of personal data and for the exercise of data subjects' rights.

2. The controller shall provide any information and any communication relating to the processing of personal data to the data subject in an intelligible form, using clear and plain language, adapted to the data subject, in particular for any information addressed specifically to a child.

Article 12
Procedures and mechanisms for exercising the rights of the data subject

1. The controller shall establish procedures for providing the information referred to in Article 14 and for the exercise of the rights of data subjects referred to in Article 13 and Articles 15 to 19. The controller shall provide in particular mechanisms for facilitating the request for the actions referred to in Article 13 and Articles 15 to 19. Where personal data are processed by automated means, the controller shall also provide means for requests to be made electronically.

2. The controller shall inform the data subject without delay and, at the latest within one month of receipt of the request, whether or not any action has been taken pursuant to Article 13 and Articles 15 to 19 and shall provide the requested information. This period may be prolonged for a further month, if several data subjects exercise their rights and their cooperation is necessary to a reasonable extent to prevent an unnecessary and disproportionate effort on the part of the controller. The information shall be given in writing. Where the data subject makes the request in electronic form, the information shall be provided in electronic form, unless otherwise requested by the data subject.

3. If the controller refuses to take action on the request of the data subject, the controller shall inform the data subject of the reasons for the refusal and on the possibilities of lodging a complaint to the supervisory authority and seeking a judicial remedy.

4. The information and the actions taken on requests referred to in paragraph 1 shall be free of charge. Where requests are manifestly excessive, in particular because of their repetitive character, the controller may charge a fee for providing the information or taking the action requested, or the controller may not take the action requested. In that case, the controller shall bear the burden of proving the manifestly excessive character of the request.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and conditions for the manifestly excessive requests and the fees referred to in paragraph 4.

6. The Commission may lay down standard forms and specifying standard procedures for the communication referred to in paragraph 2, including the electronic format. In doing so, the Commission shall take the appropriate measures for micro, small and medium-sized enterprises. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

Article 13
Rights in relation to recipients

The controller shall communicate any rectification or erasure carried out in accordance with Articles 16 and 17 to each recipient to whom the data have been disclosed, unless this proves impossible or involves a disproportionate effort.

SECTION 2
INFORMATION AND ACCESS TO DATA

Article 14
Information to the data subject

1. Where personal data relating to a data subject are collected, the controller shall provide the data subject with at least the following information:

   (a) the identity and the contact details of the controller and, if any, of the controller's representative and of the data protection officer;

   (b) the purposes of the processing for which the personal data are intended, including the contract terms and general conditions where the processing is based on point (b) of Article 6(1) and the legitimate interests pursued by the controller where the processing is based on point (f) of Article 6(1);

   (c) the period for which the personal data will be stored;

   (d) the existence of the right to request from the controller access to and rectification or erasure of the personal data concerning the data subject or to object to the processing of such personal data;

   (e) the right to lodge a complaint to the supervisory authority and the contact details of the supervisory authority;

(f) the recipients or categories of recipients of the personal data;

(g) where applicable, that the controller intends to transfer to a third country or international organisation and on the level of protection afforded by that third country or international organisation by reference to an adequacy decision by the Commission;

(h) any further information necessary to guarantee fair processing in respect of the data subject, having regard to the specific circumstances in which the personal data are collected.

2. Where the personal data are collected from the data subject, the controller shall inform the data subject, in addition to the information referred to in paragraph 1, whether the provision of personal data is obligatory or voluntary, as well as the possible consequences of failure to provide such data.

3. Where the personal data are not collected from the data subject, the controller shall inform the data subject, in addition to the information referred to in paragraph 1, from which source the personal data originate.

4. The controller shall provide the information referred to in paragraphs 1, 2 and 3:

(a) at the time when the personal data are obtained from the data subject; or

(b) where the personal data are not collected from the data subject, at the time of the recording or within a reasonable period after the collection, having regard to the specific circumstances in which the data are collected or otherwise processed, or, if a disclosure to another recipient is envisaged, and at the latest when the data are first disclosed.

5. Paragraphs 1 to 4 shall not apply, where:

(a) the data subject has already the information referred to in paragraphs 1, 2 and 3; or

(b) the data are not collected from the data subject and the provision of such information proves impossible or would involve a disproportionate effort; or

(c) the data are not collected from the data subject and recording or disclosure is expressly laid down by law; or

(d) the data are not collected from the data subject and the provision of such information will impair the rights and freedoms of others, as defined in Union law or Member State law in accordance with Article 21.

6. In the case referred to in point (b) of paragraph 5, the controller shall provide appropriate measures to protect the data subject's legitimate interests.

7. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria for categories of recipients referred to in point (f) of paragraph 1, the requirements for the notice of potential access referred to in point (g) of paragraph 1, the criteria for the further

information necessary referred to in point (h) of paragraph 1 for specific sectors and situations, and the conditions and appropriate safeguards for the exceptions laid down in point (b) of paragraph 5. In doing so, the Commission shall take the appropriate measures for micro, small and medium-sized-enterprises.

8. The Commission may lay down standard forms for providing the information referred to in paragraphs 1 to 3, taking into account the specific characteristics and needs of various sectors and data processing situations where necessary. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

Article 15

Right of access for the data subject

1. The data subject shall have the right to obtain from the controller at any time, on request, confirmation as to whether or not personal data relating to the data subject are being processed. Where such personal data are being processed, the controller shall provide the following information:

(a) the purposes of the processing;

(b) the categories of personal data concerned;

(c) the recipients or categories of recipients to whom the personal data are to be or have been disclosed, in particular to recipients in third countries;

(d) the period for which the personal data will be stored;

(e) the existence of the right to request from the controller rectification or erasure of personal data concerning the data subject or to object to the processing of such personal data;

(f) the right to lodge a complaint to the supervisory authority and the contact details of the supervisory authority;

(g) communication of the personal data undergoing processing and of any available information as to their source;

(h) the significance and envisaged consequences of such processing, at least in the case of measures referred to in Article 20.

2. The data subject shall have the right to obtain from the controller communication of the personal data undergoing processing. Where the data subject makes the request in electronic form, the information shall be provided in electronic form, unless otherwise requested by the data subject.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the communication to the data subject of the content of the personal data referred to in point (g) of paragraph 1.

4. The Commission may specify standard forms and procedures for requesting and granting access to the information referred to in paragraph 1, including for verification of the identity of the data subject and communicating the personal data to the data subject, taking into account the specific features and necessities of various sectors and data processing situations. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

SECTION 3
RECTIFICATION AND ERASURE

Article 16
Right to rectification

The data subject shall have the right to obtain from the controller the rectification of personal data relating to them which are inaccurate. The data subject shall have the right to obtain completion of incomplete personal data, including by way of supplementing a corrective statement.

Article 17
Right to be forgotten and to erasure

1. The data subject shall have the right to obtain from the controller the erasure of personal data relating to them and the abstention from further dissemination of such data, especially in relation to personal data which are made available by the data subject while he or she was a child, where one of the following grounds applies:

   (a) the data are no longer necessary in relation to the purposes for which they were collected or otherwise processed;

   (b) the data subject withdraws consent on which the processing is based according to point (a) of Article 6(1), or when the storage period consented to has expired, and where there is no other legal ground for the processing of the data;

   (c) the data subject objects to the processing of personal data pursuant to Article 19;

   (d) the processing of the data does not comply with this Regulation for other reasons.

2. Where the controller referred to in paragraph 1 has made the personal data public, it shall take all reasonable steps, including technical measures, in relation to data for the publication of which the controller is responsible, to inform third parties which are processing such data, that a data subject requests them to erase any links to, or copy or replication of that personal data. Where the controller has authorised a third party publication of personal data, the controller shall be considered responsible for that publication.

3. The controller shall carry out the erasure without delay, except to the extent that the retention of the personal data is necessary:

(a) for exercising the right of freedom of expression in accordance with Article 80;

(b) for reasons of public interest in the area of public health in accordance with Article 81;

(c) for historical, statistical and scientific research purposes in accordance with Article 83;

(d) for compliance with a legal obligation to retain the personal data by Union or Member State law to which the controller is subject; Member State laws shall meet an objective of public interest, respect the essence of the right to the protection of personal data and be proportionate to the legitimate aim pursued;

(e) in the cases referred to in paragraph 4.

4. Instead of erasure, the controller shall restrict processing of personal data where:

(a) their accuracy is contested by the data subject, for a period enabling the controller to verify the accuracy of the data;

(b) the controller no longer needs the personal data for the accomplishment of its task but they have to be maintained for purposes of proof;

(c) the processing is unlawful and the data subject opposes their erasure and requests the restriction of their use instead;

(d) the data subject requests to transmit the personal data into another automated processing system in accordance with Article 18(2).

5. Personal data referred to in paragraph 4 may, with the exception of storage, only be processed for purposes of proof, or with the data subject's consent, or for the protection of the rights of another natural or legal person or for an objective of public interest.

6. Where processing of personal data is restricted pursuant to paragraph 4, the controller shall inform the data subject before lifting the restriction on processing.

7. The controller shall implement mechanisms to ensure that the time limits established for the erasure of personal data and/or for a periodic review of the need for the storage of the data are observed.

8. Where the erasure is carried out, the controller shall not otherwise process such personal data.

9. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying:

(a) the criteria and requirements for the application of paragraph 1 for specific sectors and in specific data processing situations;

(b) the conditions for deleting links, copies or replications of personal data from publicly available communication services as referred to in paragraph 2;

(c) the criteria and conditions for restricting the processing of personal data referred to in paragraph 4.

Article 18
Right to data portability

1. The data subject shall have the right, where personal data are processed by electronic means and in a structured and commonly used format, to obtain from the controller a copy of data undergoing processing in an electronic and structured format which is commonly used and allows for further use by the data subject.

2. Where the data subject has provided the personal data and the processing is based on consent or on a contract, the data subject shall have the right to transmit those personal data and any other information provided by the data subject and retained by an automated processing system, into another one, in an electronic format which is commonly used, without hindrance from the controller from whom the personal data are withdrawn.

3. The Commission may specify the electronic format referred to in paragraph 1 and the technical standards, modalities and procedures for the transmission of personal data pursuant to paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

SECTION 4
RIGHT TO OBJECT AND PROFILING

Article 19
Right to object

1. The data subject shall have the right to object, on grounds relating to their particular situation, at any time to the processing of personal data which is based on points (d), (e) and (f) of Article 6(1), unless the controller demonstrates compelling legitimate grounds for the processing which override the interests or fundamental rights and freedoms of the data subject.

2. Where personal data are processed for direct marketing purposes, the data subject shall have the right to object free of charge to the processing of their personal data for such marketing. This right shall be explicitly offered to the data subject in an intelligible manner and shall be clearly distinguishable from other information.

3. Where an objection is upheld pursuant to paragraphs 1 and 2, the controller shall no longer use or otherwise process the personal data concerned.

Article 20
Measures based on profiling

1. Every natural person shall have the right not to be subject to a measure which produces legal effects concerning this natural person or significantly affects this natural person, and which is based solely on automated processing intended to evaluate certain personal aspects relating to this natural person or to analyse or predict in particular the natural person's performance at work, economic situation, location, health, personal preferences, reliability or behaviour.

2. Subject to the other provisions of this Regulation, a person may be subjected to a measure of the kind referred to in paragraph 1 only if the processing:

   (a) is carried out in the course of the entering into, or performance of, a contract, where the request for the entering into or the performance of the contract, lodged by the data subject, has been satisfied or where suitable measures to safeguard the data subject's legitimate interests have been adduced, such as the right to obtain human intervention; or

   (b) is expressly authorized by a Union or Member State law which also lays down suitable measures to safeguard the data subject's legitimate interests; or

   (c) is based on the data subject's consent, subject to the conditions laid down in Article 7 and to suitable safeguards.

3. Automated processing of personal data intended to evaluate certain personal aspects relating to a natural person shall not be based solely on the special categories of personal data referred to in Article 9.

4. In the cases referred to in paragraph 2, the information to be provided by the controller under Article 14 shall include information as to the existence of processing for a measure of the kind referred to in paragraph 1 and the envisaged effects of such processing on the data subject.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and conditions for suitable measures to safeguard the data subject's legitimate interests referred to in paragraph 2.

SECTION 5
RESTRICTIONS

Article 21
Restrictions

1. Union or Member State law may restrict by way of a legislative measure the scope of the obligations and rights provided for in points (a) to (e) of Article 5 and Articles 11 to 20 and Article 32, when such a restriction constitutes a necessary and proportionate measure in a democratic society to safeguard:

(a) public security;

(b) the prevention, investigation, detection and prosecution of criminal offences;

(c) other public interests of the Union or of a Member State, in particular an important economic or financial interest of the Union or of a Member State, including monetary, budgetary and taxation matters and the protection of market stability and integrity;

(d) the prevention, investigation, detection and prosecution of breaches of ethics for regulated professions;

(e) a monitoring, inspection or regulatory function connected, even occasionally, with the exercise of official authority in cases referred to in (a), (b), (c) and (d);

(f) the protection of the data subject or the rights and freedoms of others.

2. In particular, any legislative measure referred to in paragraph 1 shall contain specific provisions at least as to the objectives to be pursued by the processing and the determination of the controller.

CHAPTER IV
CONTROLLER AND PROCESSOR

SECTION 1
GENERAL OBLIGATIONS

Article 22
Responsibility of the controller

1. The controller shall adopt policies and implement appropriate measures to ensure and be able to demonstrate that the processing of personal data is performed in compliance with this Regulation.

2. The measures provided for in paragraph 1 shall in particular include:

(a) keeping the documentation pursuant to Article 28;

(b) implementing the data security requirements laid down in Article 30;

(c) performing a data protection impact assessment pursuant to Article 33;

(d) complying with the requirements for prior authorisation or prior consultation of the supervisory authority pursuant to Article 34(1) and (2);

(e) designating a data protection officer pursuant to Article 35(1).

3. The controller shall implement mechanisms to ensure the verification of the effectiveness of the measures referred to in paragraphs 1 and 2. If proportionate, this verification shall be carried out by independent internal or external auditors.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of specifying any further criteria and requirements for appropriate measures referred to in paragraph 1 other than those already referred to in paragraph 2, the conditions for the verification and auditing mechanisms referred to in paragraph 3 and as regards the criteria for proportionality under paragraph 3, and considering specific measures for micro, small and medium-sized-enterprises.

Article 23
Data protection by design and by default

1. Having regard to the state of the art and the cost of implementation, the controller shall, both at the time of the determination of the means for processing and at the time of the processing itself, implement appropriate technical and organisational measures and procedures in such a way that the processing will meet the requirements of this Regulation and ensure the protection of the rights of the data subject.

2. The controller shall implement mechanisms for ensuring that, by default, only those personal data are processed which are necessary for each specific purpose of the processing and are especially not collected or retained beyond the minimum necessary for those purposes, both in terms of the amount of the data and the time of their storage. In particular, those mechanisms shall ensure that by default personal data are not made accessible to an indefinite number of individuals.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of specifying any further criteria and requirements for appropriate measures and mechanisms referred to in paragraph 1 and 2, in particular for data protection by design requirements applicable across sectors, products and services.

4. The Commission may lay down technical standards for the requirements laid down in paragraph 1 and 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

Article 24
Joint controllers

Where a controller determines the purposes, conditions and means of the processing of personal data jointly with others, the joint controllers shall determine their respective responsibilities for compliance with the obligations under this Regulation, in particular as regards the procedures and mechanisms for exercising the rights of the data subject, by means of an arrangement between them.

Article 25
Representatives of controllers not established in the Union

1. In the situation referred to in Article 3(2), the controller shall designate a representative in the Union.

2. This obligation shall not apply to:

(a) a controller established in a third country where the Commission has decided that the third country ensures an adequate level of protection in accordance with Article 41; or

(b) an enterprise employing fewer than 250 persons; or

(c) a public authority or body; or

(d) a controller offering only occasionally goods or services to data subjects residing in the Union.

3. The representative shall be established in one of those Member States where the data subjects whose personal data are processed in relation to the offering of goods or services to them, or whose behaviour is monitored, reside.

4. The designation of a representative by the controller shall be without prejudice to legal actions which could be initiated against the controller itself.

Article 26
Processor

1. Where a processing operation is to be carried out on behalf of a controller, the controller shall choose a processor providing sufficient guarantees to implement appropriate technical and organisational measures and procedures in such a way that the processing will meet the requirements of this Regulation and ensure the protection of the rights of the data subject, in particular in respect of the technical security measures and organizational measures governing the processing to be carried out and shall ensure compliance with those measures.

2. The carrying out of processing by a processor shall be governed by a contract or other legal act binding the processor to the controller and stipulating in particular that the processor shall:

(a) act only on instructions from the controller, in particular, where the transfer of the personal data used is prohibited;

(b) employ only staff who have committed themselves to confidentiality or are under a statutory obligation of confidentiality;

(c) take all required measures pursuant to Article 30;

(d) enlist another processor only with the prior permission of the controller;

(e) insofar as this is possible given the nature of the processing, create in agreement with the controller the necessary technical and organisational requirements for the fulfilment of the controller's obligation to respond to requests for exercising the data subject's rights laid down in Chapter III;

(f) assist the controller in ensuring compliance with the obligations pursuant to Articles 30 to 34;

(g) hand over all results to the controller after the end of the processing and not process the personal data otherwise;

(h) make available to the controller and the supervisory authority all information necessary to control compliance with the obligations laid down in this Article.

3. The controller and the processor shall document in writing the controller's instructions and the processor's obligations referred to in paragraph 2.

4. If a processor processes personal data other than as instructed by the controller, the processor shall be considered to be a controller in respect of that processing and shall be subject to the rules on joint controllers laid down in Article 24.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the responsibilities, duties and tasks in relation to a processor in line with paragraph 1, and conditions which allow facilitating the processing of personal data within a group of undertakings, in particular for the purposes of control and reporting.

Article 27

Processing under the authority of the controller and processor

The processor and any person acting under the authority of the controller or of the processor who has access to personal data shall not process them except on instructions from the controller, unless required to do so by Union or Member State law.

Article 28

Documentation

1. Each controller and processor and, if any, the controller's representative, shall maintain documentation of all processing operations under its responsibility.

2. The documentation shall contain at least the following information:

(a) the name and contact details of the controller, or any joint controller or processor, and of the representative, if any;

(b) the name and contact details of the data protection officer, if any;

(c) the purposes of the processing, including the legitimate interests pursued by the controller where the processing is based on point (f) of Article 6(1);

(d) a description of categories of data subjects and of the categories of personal data relating to them;

(e) the recipients or categories of recipients of the personal data, including the controllers to whom personal data are disclosed for the legitimate interest pursued by them;

(f) where applicable, transfers of data to a third country or an international organisation, including the identification of that third country or international organisation and, in case of transfers referred to in point (h) of Article 44(1), the documentation of appropriate safeguards;

(g) a general indication of the time limits for erasure of the different categories of data;

(h) the description of the mechanisms referred to in Article 22(3).

3. The controller and the processor and, if any, the controller's representative, shall make the documentation available, on request, to the supervisory authority.

4. The obligations referred to in paragraphs 1 and 2 shall not apply to the following controllers and processors:

(a) a natural person processing personal data without a commercial interest; or

(b) an enterprise or an organisation employing fewer than 250 persons that is processing personal data only as an activity ancillary to its main activities.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the documentation referred to in paragraph 1, to take account of in particular the responsibilities of the controller and the processor and, if any, the controller's representative.

6. The Commission may lay down standard forms for the documentation referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

Article 29

Co-operation with the supervisory authority

1. The controller and the processor and, if any, the representative of the controller, shall co-operate, on request, with the supervisory authority in the performance of its duties, in particular by providing the information referred to in point (a) of Article 53(2) and by granting access as provided in point (b) of that paragraph.

2. In response to the supervisory authority's exercise of its powers under Article 53(2), the controller and the processor shall reply to the supervisory authority within a reasonable period to be specified by the supervisory authority. The reply shall include a description of the measures taken and the results achieved, in response to the remarks of the supervisory authority.

SECTION 2
DATA SECURITY

Article 30
Security of processing

1. The controller and the processor shall implement appropriate technical and organisational measures to ensure a level of security appropriate to the risks represented by the processing and the nature of the personal data to be protected, having regard to the state of the art and the costs of their implementation.

2. The controller and the processor shall, following an evaluation of the risks, take the measures referred to in paragraph 1 to protect personal data against accidental or unlawful destruction or accidental loss and to prevent any unlawful forms of processing, in particular any unauthorised disclosure, dissemination or access, or alteration of personal data.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and conditions for the technical and organisational measures referred to in paragraphs 1 and 2, including the determinations of what constitutes the state of the art, for specific sectors and in specific data processing situations, in particular taking account of developments in technology and solutions for privacy by design and data protection by default, unless paragraph 4 applies.

4. The Commission may adopt, where necessary, implementing acts for specifying the requirements laid down in paragraphs 1 and 2 to various situations, in particular to:

   (a) prevent any unauthorised access to personal data;

   (b) prevent any unauthorised disclosure, reading, copying, modification, erasure or removal of personal data;

   (c) ensure the verification of the lawfulness of processing operations.

   Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

Article 31
Notification of a personal data breach to the supervisory authority

1. In the case of a personal data breach, the controller shall without undue delay and, where feasible, not later than 24 hours after having become aware of it, notify the personal data breach to the supervisory authority. The notification to the supervisory authority shall be accompanied by a reasoned justification in cases where it is not made within 24 hours.

2. Pursuant to point (f) of Article 26(2), the processor shall alert and inform the controller immediately after the establishment of a personal data breach.

3. The notification referred to in paragraph 1 must at least:

(a) describe the nature of the personal data breach including the categories and number of data subjects concerned and the categories and number of data records concerned;

(b) communicate the identity and contact details of the data protection officer or other contact point where more information can be obtained;

(c) recommend measures to mitigate the possible adverse effects of the personal data breach;

(d) describe the consequences of the personal data breach;

(e) describe the measures proposed or taken by the controller to address the personal data breach.

4. The controller shall document any personal data breaches, comprising the facts surrounding the breach, its effects and the remedial action taken. This documentation must enable the supervisory authority to verify compliance with this Article. The documentation shall only include the information necessary for that purpose.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for establishing the data breach referred to in paragraphs 1 and 2 and for the particular circumstances in which a controller and a processor is required to notify the personal data breach.

6. The Commission may lay down the standard format of such notification to the supervisory authority, the procedures applicable to the notification requirement and the form and the modalities for the documentation referred to in paragraph 4, including the time limits for erasure of the information contained therein. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

Article 32

Communication of a personal data breach to the data subject

1. When the personal data breach is likely to adversely affect the protection of the personal data or privacy of the data subject, the controller shall, after the notification referred to in Article 31, communicate the personal data breach to the data subject without undue delay.

2. The communication to the data subject referred to in paragraph 1 shall describe the nature of the personal data breach and contain at least the information and the recommendations provided for in points (b) and (c) of Article 31(3).

3. The communication of a personal data breach to the data subject shall not be required if the controller demonstrates to the satisfaction of the supervisory authority that it has implemented appropriate technological protection measures, and that those measures were applied to the data concerned by the personal data breach. Such

technological protection measures shall render the data unintelligible to any person who is not authorised to access it.

4. Without prejudice to the controller's obligation to communicate the personal data breach to the data subject, if the controller has not already communicated the personal data breach to the data subject of the personal data breach, the supervisory authority, having considered the likely adverse effects of the breach, may require it to do so.

5. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements as to the circumstances in which a personal data breach is likely to adversely affect the personal data referred to in paragraph 1.

6. The Commission may lay down the format of the communication to the data subject referred to in paragraph 1 and the procedures applicable to that communication. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

SECTION 3
DATA PROTECTION IMPACT ASSESSMENT AND PRIOR AUTHORISATION

Article 33
Data protection impact assessment

1. Where processing operations present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes, the controller or the processor acting on the controller's behalf shall carry out an assessment of the impact of the envisaged processing operations on the protection of personal data.

2. The following processing operations in particular present specific risks referred to in paragraph 1:

   (a) a systematic and extensive evaluation of personal aspects relating to a natural person or for analysing or predicting in particular the natural person's economic situation, location, health, personal preferences, reliability or behaviour, which is based on automated processing and on which measures are based that produce legal effects concerning the individual or significantly affect the individual;

   (b) information on sex life, health, race and ethnic origin or for the provision of health care, epidemiological researches, or surveys of mental or infectious diseases, where the data are processed for taking measures or decisions regarding specific individuals on a large scale;

   (c) monitoring publicly accessible areas, especially when using optic-electronic devices (video surveillance) on a large scale;

   (d) personal data in large scale filing systems on children, genetic data or biometric data;

(e) other processing operations for which the consultation of the supervisory authority is required pursuant to point (b) of Article 34(2).

3. The assessment shall contain at least a general description of the envisaged processing operations, an assessment of the risks to the rights and freedoms of data subjects, the measures envisaged to address the risks, safeguards, security measures and mechanisms to ensure the protection of personal data and to demonstrate compliance with this Regulation, taking into account the rights and legitimate interests of data subjects and other persons concerned.

4. The controller shall seek the views of data subjects or their representatives on the intended processing, without prejudice to the protection of commercial or public interests or the security of the processing operations.

5. Where the controller is a public authority or body and where the processing results from a legal obligation pursuant to point (c) of Article 6(1) providing for rules and procedures pertaining to the processing operations and regulated by Union law, paragraphs 1 to 4 shall not apply, unless Member States deem it necessary to carry out such assessment prior to the processing activities.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and conditions for the processing operations likely to present specific risks referred to in paragraphs 1 and 2 and the requirements for the assessment referred to in paragraph 3, including conditions for scalability, verification and auditability. In doing so, the Commission shall consider specific measures for micro, small and medium-sized enterprises.

7. The Commission may specify standards and procedures for carrying out and verifying and auditing the assessment referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).

Article 34

Prior authorisation and prior consultation

1. The controller or the processor as the case may be shall obtain an authorisation from the supervisory authority prior to the processing of personal data, in order to ensure the compliance of the intended processing with this Regulation and in particular to mitigate the risks involved for the data subjects where a controller or processor adopts contractual clauses as provided for in point (d) of Article 42(2) or does not provide for the appropriate safeguards in a legally binding instrument as referred to in Article 42(5) for the transfer of personal data to a third country or an international organisation.

2. The controller or processor acting on the controller's behalf shall consult the supervisory authority prior to the processing of personal data in order to ensure the compliance of the intended processing with this Regulation and in particular to mitigate the risks involved for the data subjects where:

(a) a data protection impact assessment as provided for in Article 33 indicates that processing operations are by virtue of their nature, their scope or their purposes, likely to present a high degree of specific risks; or

(b) the supervisory authority deems it necessary to carry out a prior consultation on processing operations that are likely to present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope and/or their purposes, and specified according to paragraph 4.

3. Where the supervisory authority is of the opinion that the intended processing does not comply with this Regulation, in particular where risks are insufficiently identified or mitigated, it shall prohibit the intended processing and make appropriate proposals to remedy such incompliance.

4. The supervisory authority shall establish and make public a list of the processing operations which are subject to prior consultation pursuant to point (b) of paragraph 2. The supervisory authority shall communicate those lists to the European Data Protection Board.

5. Where the list provided for in paragraph 4 involves processing activities which are related to the offering of goods or services to data subjects in several Member States, or to the monitoring of their behaviour, or may substantially affect the free movement of personal data within the Union, the supervisory authority shall apply the consistency mechanism referred to in Article 57 prior to the adoption of the list.

6. The controller or processor shall provide the supervisory authority with the data protection impact assessment provided for in Article 33 and, on request, with any other information to allow the supervisory authority to make an assessment of the compliance of the processing and in particular of the risks for the protection of personal data of the data subject and of the related safeguards.

7. Member States shall consult the supervisory authority in the preparation of a legislative measure to be adopted by the national parliament or of a measure based on such a legislative measure, which defines the nature of the processing, in order to ensure the compliance of the intended processing with this Regulation and in particular to mitigate the risks involved for the data subjects.

8. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for determining the high degree of specific risk referred to in point (a) of paragraph 2.

9. The Commission may set out standard forms and procedures for prior authorisations and consultations referred to in paragraphs 1 and 2, and standard forms and procedures for informing the supervisory authorities pursuant to paragraph 6. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).