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tant economic or financial interests of a Member State or the Union, as well as criminal investigations and prosecutions and action in respect of breaches of ethics in the regulated professions; whereas the list of exceptions and limitations should include the tasks of monitoring, inspection or regulation necessary in the three last-mentioned areas concerning public security, economic or financial interests and crime prevention; whereas the listing of tasks in these three areas does not affect the legitimacy of exceptions or restrictions for reasons of State security or defence;

- (44) Whereas Member States may also be led, by virtue of the provisions of Community law, to derogate from the provisions of this Directive concerning the right of access, the obligation to inform individuals, and the quality of data, in order to secure certain of the purposes referred to above;
- (45) Whereas, in cases where data might lawfully be processed on grounds of public interest, official authority or the legitimate interests of a natural or legal person, any data subject should nevertheless be entitled, on legitimate and compelling grounds relating to his particular situation, to object to the processing of any data relating to himself; whereas Member States may nevertheless lay down national provisions to the contrary;
- (46) Whereas the protection of the rights and freedoms of data subjects with regard to the processing of personal data requires that appropriate technical and organizational measures be taken, both at the time of the design of the processing system and at the time of the processing itself, particularly in order to maintain security and thereby to prevent any unauthorized processing; whereas it is incumbent on the Member States to ensure that controllers comply with these measures; whereas these measures must 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 inherent in the processing and the nature of the data to be protected;
- (47) Whereas where a message containing personal data is transmitted by means of a telecommunications or electronic mail service, the sole purpose of which is the transmission of such messages, the controller in respect of the personal data contained in the message will normally be considered to be the person from whom the message originates, rather than the person offering the transmission services; whereas, nevertheless, those offering such services will normally be considered controllers in respect of the processing of the additional personal data necessary for the operation of the service;
- (48) Whereas the procedures for notifying the supervisory authority are designed to ensure disclosure of the purposes and main features of any processing operation for the purpose of verification that the operation is in accordance with the national measures taken under this Directive;
- (49) Whereas, in order to avoid unsuitable administrative formalities, exemptions from the obligation to notify and simplification of the notification required may be provided for by Member States in cases where processing is unlikely adversely to affect the rights and freedoms of data subjects, provided that it is in accordance with a measure taken by a Member State specifying its limits; whereas exemption or simplification may similarly be provided for by Member States where a person appointed by the controller ensures that the processing carried out is not likely adversely to affect the rights and freedoms of data subjects; whereas such a data protection official, whether or not an employee of the controller, must be in a position to exercise his functions in complete independence;
- (50) Whereas exemption or simplification could be provided for in cases of processing operations whose sole purpose is the keeping of a register intended, according to national law, to provide

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- information to the public and open to consultation by the public or by any person demonstrating a legitimate interest;
- (51) Whereas, nevertheless, simplification or exemption from the obligation to notify shall not release the controller from any of the other obligations resulting from this Directive;
- (52) Whereas, in this context, *ex post facto* verification by the competent authorities must in general be considered a sufficient measure;
- (53) Whereas, however, certain processing operations are likely to pose specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes, such as that of excluding individuals from a right, benefit or a contract, or by virtue of the specific use of new technologies; whereas it is for Member States, if they so wish, to specify such risks in their legislation;
- (54) Whereas with regard to all the processing undertaken in society, the amount posing such specific risks should be very limited; whereas Member States must provide that the supervisory authority, or the data protection official in cooperation with the authority, check such processing prior to it being carried out; whereas following this prior check, the supervisory authority may, according to its national law, give an opinion or an authorization regarding the processing; whereas such checking may equally take place in the course of the preparation either of a measure of the national parliament or of a measure based on such a legislative measure, which defines the nature of the processing and lays down appropriate safeguards;
- (55) Whereas, if the controller fails to respect the rights of data subjects, national legislation must provide for a judicial remedy; whereas any damage which a person may suffer as a result of unlawful processing must be compensated for by the controller, who may be exempted from liability if he proves that he is not responsible for the damage, in particular in cases where he establishes fault on the part of the data subject or in case of *force majeure*; whereas sanctions must be imposed on any person, whether governed by private or public law, who fails to comply with the national measures taken under this Directive;
- (56) Whereas cross-border flows of personal data are necessary to the expansion of international trade; whereas the protection of individuals guaranteed in the Community by this Directive does not stand in the way of transfers of personal data to third countries which ensure an adequate level of protection; whereas the adequacy of the level of protection afforded by a third country must be assessed in the light of all the circumstances surrounding the transfer operation or set of transfer operations;
- (57) Whereas, on the other hand, the transfer of personal data to a third country which does not ensure an adequate level of protection must be prohibited;
- (58) Whereas provisions should be made for exemptions from this prohibition 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 protection of an important public interest so requires, for example in cases of international transfers of data between tax or customs administrations or between services competent for social security matters, 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; whereas in this 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;

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- (59) Whereas particular measures may be taken to compensate for the lack of protection in a third country in cases where the controller offers appropriate safeguards; whereas, moreover, provision must be made for procedures for negotiations between the Community and such third countries;
- (60) Whereas, in any event, transfers to third countries may be effected only in full compliance with the provisions adopted by the Member States pursuant to this Directive, and in particular Article 8 thereof;
- (61) Whereas Member States and the Commission, in their respective spheres of competence, must encourage the trade associations and other representative organizations concerned to draw up codes of conduct so as to facilitate the application of this Directive, taking account of the specific characteristics of the processing carried out in certain sectors, and respecting the national provisions adopted for its implementation;
- (62) Whereas the establishment in Member States of supervisory authorities, exercising their functions with complete independence, is an essential component of the protection of individuals with regard to the processing of personal data;
- (63) Whereas such authorities must have the necessary means to perform their duties, including powers of investigation and intervention, particularly in cases of complaints from individuals, and powers to engage in legal proceedings; whereas such authorities must help to ensure transparency of processing in the Member States within whose jurisdiction they fall;
- (64) Whereas the authorities in the different Member States will need to assist one another in performing their duties so as to ensure that the rules of protection are properly respected throughout the European Union;
- (65) Whereas, at Community level, a Working Party on the Protection of Individuals with regard to the Processing of Personal Data must be set up and be completely independent in the performance of its functions; whereas, having regard to its specific nature, it must advise the Commission and, in particular, contribute to the uniform application of the national rules adopted pursuant to this Directive;
- (66) Whereas, with regard to the transfer of data to third countries, the application of this Directive calls for the conferment of powers of implementation on the Commission and the establishment of a procedure as laid down in Council Decision 87/373/EEC ⁽¹⁾;
- (67) Whereas an agreement on a *modus vivendi* between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the EC Treaty was reached on 20 December 1994;
- (68) Whereas the principles set out in this Directive regarding the protection of the rights and freedoms of individuals, notably their right to privacy, with regard to the processing of personal data may be supplemented or clarified, in particular as far as certain sectors are concerned, by specific rules based on those principles;
- (69) Whereas Member States should be allowed a period of not more than three years from the entry into force of the national measures transposing this Directive in which to apply such new national rules progressively to all processing operations already under way; whereas, in order to facilitate their cost-effective implementation, a further period expiring 12 years after the date on which this Directive is adopted will be allowed to Member States to ensure the conformity of existing manual filing systems

⁽¹⁾ OJ No L 197, 18. 7. 1987, p. 33.

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with certain of the Directive's provisions; whereas, where data contained in such filing systems are manually processed during this extended transition period, those systems must be brought into conformity with these provisions at the time of such processing;

- (70) Whereas it is not necessary for the data subject to give his consent again so as to allow the controller to continue to process, after the national provisions taken pursuant to this Directive enter into force, any sensitive data necessary for the performance of a contract concluded on the basis of free and informed consent before the entry into force of these provisions;
- (71) Whereas this Directive does not stand in the way of a Member State's regulating marketing activities aimed at consumers residing in territory in so far as such regulation does not concern the protection of individuals with regard to the processing of personal data;
- (72) Whereas this Directive allows the principle of public access to official documents to be taken into account when implementing the principles set out in this Directive,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

*Article 1***Object of the Directive**

1. In accordance with this Directive, Member States shall protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data.
2. Member States shall neither restrict nor prohibit the free flow of personal data between Member States for reasons connected with the protection afforded under paragraph 1.

*Article 2***Definitions**

For the purposes of this Directive:

- (a) 'personal data' shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity;
- (b) 'processing of personal data' ('processing') shall mean any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction;
- (c) 'personal data filing system' ('filing system') shall mean any structured set of personal data which are accessible according to specific criteria, whether centralized, decentralized or dispersed on a functional or geographical basis;
- (d) 'controller' shall mean the natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data; where the purposes and means of processing are determined by national or Community laws or regulations, the controller or the specific criteria for his nomination may be designated by national or Community law;

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- (e) 'processor' shall mean a natural or legal person, public authority, agency or any other body which processes personal data on behalf of the controller;
- (f) 'third party' shall mean any natural or legal person, public authority, agency or any other body other than the data subject, the controller, the processor and the persons who, under the direct authority of the controller or the processor, are authorized to process the data;
- (g) 'recipient' shall mean a natural or legal person, public authority, agency or any other body to whom data are disclosed, whether a third party or not; however, authorities which may receive data in the framework of a particular inquiry shall not be regarded as recipients;
- (h) 'the data subject's consent' shall mean any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed.

*Article 3***Scope**

1. This Directive shall apply to the processing of personal data wholly or partly by automatic means, and to the processing otherwise than by automatic means of personal data which form part of a filing system or are intended to form part of a filing system.
2. This Directive shall not apply to the processing of personal data:
 - in the course of an activity which falls outside the scope of Community law, such as those provided for by Titles V and VI of the Treaty on European Union and in any case to processing operations concerning public security, defence, State security (including the economic well-being of the State when the processing operation relates to State security matters) and the activities of the State in areas of criminal law,
 - by a natural person in the course of a purely personal or household activity.

*Article 4***National law applicable**

1. Each Member State shall apply the national provisions it adopts pursuant to this Directive to the processing of personal data where:
 - (a) the processing is carried out in the context of the activities of an establishment of the controller on the territory of the Member State; when the same controller is established on the territory of several Member States, he must take the necessary measures to ensure that each of these establishments complies with the obligations laid down by the national law applicable;
 - (b) the controller is not established on the Member State's territory, but in a place where its national law applies by virtue of international public law;
 - (c) the controller is not established on Community territory and, for purposes of processing personal data makes use of equipment, automated or otherwise, situated on the territory of the said Member State, unless such equipment is used only for purposes of transit through the territory of the Community.
2. In the circumstances referred to in paragraph 1 (c), the controller must designate a representative established in the territory of that Member State, without prejudice to legal actions which could be initiated against the controller himself.

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CHAPTER II

GENERAL RULES ON THE LAWFULNESS OF THE PROCESSING OF PERSONAL DATA*Article 5*

Member States shall, within the limits of the provisions of this Chapter, determine more precisely the conditions under which the processing of personal data is lawful.

SECTION I

PRINCIPLES RELATING TO DATA QUALITY*Article 6*

1. Member States shall provide that personal data must be:
 - (a) processed fairly and lawfully;
 - (b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards;
 - (c) adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed;
 - (d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified;
 - (e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use.
2. It shall be for the controller to ensure that paragraph 1 is complied with.

SECTION II

CRITERIA FOR MAKING DATA PROCESSING LEGITIMATE*Article 7*

Member States shall provide that personal data may be processed only if:

- (a) the data subject has unambiguously given his consent; or
- (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; or
- (c) processing is necessary for compliance with a legal obligation to which the controller is subject; or
- (d) processing is necessary in order to protect the vital interests of the data subject; or
- (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 or in a third party to whom the data are disclosed; or
- (f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except where such interests are overridden by the interests for fundamental rights and freedoms of the data subject which require protection under Article 1 (1).



SECTION III

SPECIAL CATEGORIES OF PROCESSING

Article 8

The processing of special categories of data

1. Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.
 2. Paragraph 1 shall not apply where:
 - (a) the data subject has given his explicit consent to the processing of those data, except where the laws of the Member State provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject's giving his consent; or
 - (b) processing is necessary for the purposes of carrying out the obligations and specific rights of the controller in the field of employment law in so far as it is authorized by national 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 his consent; or
 - (d) processing is carried out in the course of its legitimate activities with appropriate guarantees 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 of the body or to persons who have regular contact with it in connection with its purposes and that the data are not disclosed to a third party without the consent of the data subjects; or
 - (e) the processing relates to data which are manifestly made public by the data subject or is necessary for the establishment, exercise or defence of legal claims.
 3. Paragraph 1 shall not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.
 4. Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority.
 5. Processing of data relating to offences, criminal convictions or security measures may be carried out only under the control of official authority, or if suitable specific safeguards are provided under national law, subject to derogations which may be granted by the Member State under national provisions providing suitable specific safeguards. However, a complete register of criminal convictions may be kept only under the control of official authority.
- Member States may provide that data relating to administrative sanctions or judgements in civil cases shall also be processed under the control of official authority.
6. Derogations from paragraph 1 provided for in paragraphs 4 and 5 shall be notified to the Commission.
 7. Member States shall determine the conditions under which a national identification number or any other identifier of general application may be processed.

▼ **B***Article 9***Processing of personal data and freedom of expression**

Member States shall provide for exemptions or derogations from the provisions of this Chapter, Chapter IV and Chapter VI for the processing of personal data carried out solely for journalistic purposes or the purpose of artistic or literary expression only if they are necessary to reconcile the right to privacy with the rules governing freedom of expression.

SECTION IV

INFORMATION TO BE GIVEN TO THE DATA SUBJECT*Article 10***Information in cases of collection of data from the data subject**

Member States shall provide that the controller or his representative must provide a data subject from whom data relating to himself are collected with at least the following information, except where he already has it:

- (a) the identity of the controller and of his representative, if any;
- (b) the purposes of the processing for which the data are intended;
- (c) any further information such as
 - the recipients or categories of recipients of the data,
 - whether replies to the questions are obligatory or voluntary, as well as the possible consequences of failure to reply,
 - the existence of the right of access to and the right to rectify the data concerning him

in so far as such further information is necessary, having regard to the specific circumstances in which the data are collected, to guarantee fair processing in respect of the data subject.

*Article 11***Information where the data have not been obtained from the data subject**

1. Where the data have not been obtained from the data subject, Member States shall provide that the controller or his representative must at the time of undertaking the recording of personal data or if a disclosure to a third party is envisaged, no later than the time when the data are first disclosed provide the data subject with at least the following information, except where he already has it:

- (a) the identity of the controller and of his representative, if any;
- (b) the purposes of the processing;
- (c) any further information such as
 - the categories of data concerned,
 - the recipients or categories of recipients,
 - the existence of the right of access to and the right to rectify the data concerning him

in so far as such further information is necessary, having regard to the specific circumstances in which the data are processed, to guarantee fair processing in respect of the data subject.

2. Paragraph 1 shall not apply where, in particular for processing for statistical purposes or for the purposes of historical or scientific research, the provision of such information proves impossible or would involve a disproportionate effort or if recording or disclosure is expressly laid down by law. In these cases Member States shall provide appropriate safeguards.



SECTION V

THE DATA SUBJECT'S RIGHT OF ACCESS TO DATA

Article 12

Right of access

Member States shall guarantee every data subject the right to obtain from the controller:

- (a) without constraint at reasonable intervals and without excessive delay or expense:
 - confirmation as to whether or not data relating to him are being processed and information at least as to the purposes of the processing, the categories of data concerned, and the recipients or categories of recipients to whom the data are disclosed,
 - communication to him in an intelligible form of the data undergoing processing and of any available information as to their source,
 - knowledge of the logic involved in any automatic processing of data concerning him at least in the case of the automated decisions referred to in Article 15 (1);
- (b) as appropriate the rectification, erasure or blocking of data the processing of which does not comply with the provisions of this Directive, in particular because of the incomplete or inaccurate nature of the data;
- (c) notification to third parties to whom the data have been disclosed of any rectification, erasure or blocking carried out in compliance with (b), unless this proves impossible or involves a disproportionate effort.

SECTION VI

EXEMPTIONS AND RESTRICTIONS

Article 13

Exemptions and restrictions

1. Member States may adopt legislative measures to restrict the scope of the obligations and rights provided for in Articles 6 (1), 10, 11 (1), 12 and 21 when such a restriction constitutes a necessary measure to safeguard:

- (a) national security;
- (b) defence;
- (c) public security;
- (d) the prevention, investigation, detection and prosecution of criminal offences, or of breaches of ethics for regulated professions;
- (e) an important economic or financial interest of a Member State or of the European Union, including monetary, budgetary and taxation matters;
- (f) a monitoring, inspection or regulatory function connected, even occasionally, with the exercise of official authority in cases referred to in (c), (d) and (e);
- (g) the protection of the data subject or of the rights and freedoms of others.

2. Subject to adequate legal safeguards, in particular that the data are not used for taking measures or decisions regarding any particular individual, Member States may, where there is clearly no risk of breaching the privacy of the data subject, restrict by a legislative measure the rights provided for in Article 12 when data are processed solely for purposes of scientific research or are kept in personal form for a period which does not exceed the period necessary for the sole purpose of creating statistics.

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SECTION VII

THE DATA SUBJECT'S RIGHT TO OBJECT*Article 14***The data subject's right to object**

Member States shall grant the data subject the right:

- (a) at least in the cases referred to in Article 7 (e) and (f), to object at any time on compelling legitimate grounds relating to his particular situation to the processing of data relating to him, save where otherwise provided by national legislation. Where there is a justified objection, the processing instigated by the controller may no longer involve those data;
- (b) to object, on request and free of charge, to the processing of personal data relating to him which the controller anticipates being processed for the purposes of direct marketing, or to be informed before personal data are disclosed for the first time to third parties or used on their behalf for the purposes of direct marketing, and to be expressly offered the right to object free of charge to such disclosures or uses.

Member States shall take the necessary measures to ensure that data subjects are aware of the existence of the right referred to in the first subparagraph of (b).

*Article 15***Automated individual decisions**

1. Member States shall grant the right to every person not to be subject to a decision which produces legal effects concerning him or significantly affects him and which is based solely on automated processing of data intended to evaluate certain personal aspects relating to him, such as his performance at work, creditworthiness, reliability, conduct, etc.
2. Subject to the other Articles of this Directive, Member States shall provide that a person may be subjected to a decision of the kind referred to in paragraph 1 if that decision:
 - (a) is taken in the course of the entering into or performance of a contract, provided the request for the entering into or the performance of the contract, lodged by the data subject, has been satisfied or that there are suitable measures to safeguard his legitimate interests, such as arrangements allowing him to put his point of view; or
 - (b) is authorized by a law which also lays down measures to safeguard the data subject's legitimate interests.

SECTION VIII

CONFIDENTIALITY AND SECURITY OF PROCESSING*Article 16***Confidentiality of processing**

Any person acting under the authority of the controller or of the processor, including the processor himself, who has access to personal data must not process them except on instructions from the controller, unless he is required to do so by law.

*Article 17***Security of processing**

1. Member States shall provide that the controller must implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, in particular where the

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processing involves the transmission of data over a network, and against all other unlawful forms of processing.

Having regard to the state of the art and the cost of their implementation, such measures shall ensure a level of security appropriate to the risks represented by the processing and the nature of the data to be protected.

2. The Member States shall provide that the controller must, where processing is carried out on his behalf, choose a processor providing sufficient guarantees in respect of the technical security measures and organizational measures governing the processing to be carried out, and must ensure compliance with those measures.

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

- the processor shall act only on instructions from the controller,
- the obligations set out in paragraph 1, as defined by the law of the Member State in which the processor is established, shall also be incumbent on the processor.

4. For the purposes of keeping proof, the parts of the contract or the legal act relating to data protection and the requirements relating to the measures referred to in paragraph 1 shall be in writing or in another equivalent form.

SECTION IX
NOTIFICATION

Article 18

Obligation to notify the supervisory authority

1. Member States shall provide that the controller or his representative, if any, must notify the supervisory authority referred to in Article 28 before carrying out any wholly or partly automatic processing operation or set of such operations intended to serve a single purpose or several related purposes.

2. Member States may provide for the simplification of or exemption from notification only in the following cases and under the following conditions:

- where, for categories of processing operations which are unlikely, taking account of the data to be processed, to affect adversely the rights and freedoms of data subjects, they specify the purposes of the processing, the data or categories of data undergoing processing, the category or categories of data subject, the recipients or categories of recipient to whom the data are to be disclosed and the length of time the data are to be stored, and/or
- where the controller, in compliance with the national law which governs him, appoints a personal data protection official, responsible in particular:
 - for ensuring in an independent manner the internal application of the national provisions taken pursuant to this Directive
 - for keeping the register of processing operations carried out by the controller, containing the items of information referred to in Article 21 (2),

thereby ensuring that the rights and freedoms of the data subjects are unlikely to be adversely affected by the processing operations.

3. Member States may provide that paragraph 1 does not apply to processing whose sole purpose is the keeping of a register which according to laws or regulations is intended to provide information to the public and which is open to consultation either by the public in general or by any person demonstrating a legitimate interest.

4. Member States may provide for an exemption from the obligation to notify or a simplification of the notification in the case of processing operations referred to in Article 8 (2) (d).

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5. Member States may stipulate that certain or all non-automatic processing operations involving personal data shall be notified, or provide for these processing operations to be subject to simplified notification.

*Article 19***Contents of notification**

1. Member States shall specify the information to be given in the notification. It shall include at least:
 - (a) the name and address of the controller and of his representative, if any;
 - (b) the purpose or purposes of the processing;
 - (c) a description of the category or categories of data subject and of the data or categories of data relating to them;
 - (d) the recipients or categories of recipient to whom the data might be disclosed;
 - (e) proposed transfers of data to third countries;
 - (f) a general description allowing a preliminary assessment to be made of the appropriateness of the measures taken pursuant to Article 17 to ensure security of processing.
2. Member States shall specify the procedures under which any change affecting the information referred to in paragraph 1 must be notified to the supervisory authority.

*Article 20***Prior checking**

1. Member States shall determine the processing operations likely to present specific risks to the rights and freedoms of data subjects and shall check that these processing operations are examined prior to the start thereof.
2. Such prior checks shall be carried out by the supervisory authority following receipt of a notification from the controller or by the data protection official, who, in cases of doubt, must consult the supervisory authority.
3. Member States may also carry out such checks in the context of preparation either of a measure of the national parliament or of a measure based on such a legislative measure, which define the nature of the processing and lay down appropriate safeguards.

*Article 21***Publicizing of processing operations**

1. Member States shall take measures to ensure that processing operations are publicized.
2. Member States shall provide that a register of processing operations notified in accordance with Article 18 shall be kept by the supervisory authority.

The register shall contain at least the information listed in Article 19 (1) (a) to (e).

The register may be inspected by any person.

3. Member States shall provide, in relation to processing operations not subject to notification, that controllers or another body appointed by the Member States make available at least the information referred to in Article 19 (1) (a) to (e) in an appropriate form to any person on request.

Member States may provide that this provision does not apply to processing whose sole purpose is the keeping of a register which according to laws or regulations is intended to provide information to

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the public and which is open to consultation either by the public in general or by any person who can provide proof of a legitimate interest.

CHAPTER III

JUDICIAL REMEDIES, LIABILITY AND SANCTIONS

*Article 22***Remedies**

Without prejudice to any administrative remedy for which provision may be made, *inter alia* before the supervisory authority referred to in Article 28, prior to referral to the judicial authority, Member States shall provide for the right of every person to a judicial remedy for any breach of the rights guaranteed him by the national law applicable to the processing in question.

*Article 23***Liability**

1. Member States shall provide that any person who has suffered damage as a result of an unlawful processing operation or of any act incompatible with the national provisions adopted pursuant to this Directive is entitled to receive compensation from the controller for the damage suffered.

2. The controller may be exempted from this liability, in whole or in part, if he proves that he is not responsible for the event giving rise to the damage.

*Article 24***Sanctions**

The Member States shall adopt suitable measures to ensure the full implementation of the provisions of this Directive and shall in particular lay down the sanctions to be imposed in case of infringement of the provisions adopted pursuant to this Directive.

CHAPTER IV

TRANSFER OF PERSONAL DATA TO THIRD COUNTRIES

*Article 25***Principles**

1. The Member States shall provide that the transfer to a third country of personal data which are undergoing processing or are intended for processing after transfer may take place only if, without prejudice to compliance with the national provisions adopted pursuant to the other provisions of this Directive, the third country in question ensures an adequate level of protection.

2. The adequacy of the level of protection afforded by a third country shall be assessed in the light of all the circumstances surrounding a data transfer operation or set of data transfer operations; particular consideration shall be given to the nature of the data, the purpose and duration of the proposed processing operation or operations, the country of origin and country of final destination, the rules of law, both general and sectoral, in force in the third country in question and the professional rules and security measures which are complied with in that country.

3. The Member States and the Commission shall inform each other of cases where they consider that a third country does not ensure an adequate level of protection within the meaning of paragraph 2.

4. Where the Commission finds, under the procedure provided for in Article 31 (2), that a third country does not ensure an adequate level of

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protection within the meaning of paragraph 2 of this Article, Member States shall take the measures necessary to prevent any transfer of data of the same type to the third country in question.

5. At the appropriate time, the Commission shall enter into negotiations with a view to remedying the situation resulting from the finding made pursuant to paragraph 4.

6. The Commission may find, in accordance with the procedure referred to in Article 31 (2), that a third country ensures an adequate level of protection within the meaning of paragraph 2 of this Article, by reason of its domestic law or of the international commitments it has entered into, particularly upon conclusion of the negotiations referred to in paragraph 5, for the protection of the private lives and basic freedoms and rights of individuals.

Member States shall take the measures necessary to comply with the Commission's decision.

Article 26

Derogations

1. By way of derogation from Article 25 and save where otherwise provided by domestic law governing particular cases, Member States shall provide that a transfer or a set of transfers of personal data to a third country which does not ensure an adequate level of protection within the meaning of Article 25 (2) may take place on condition that:

- (a) the data subject has given his consent unambiguously to the proposed transfer; or
- (b) the transfer is necessary for the performance of a contract between the data subject and the controller or the implementation of precontractual measures taken in response to the data subject's request; or
- (c) the transfer is necessary for the conclusion or performance of a contract concluded in the interest of the data subject between the controller and a third party; or
- (d) the transfer is necessary or legally required on important public interest grounds, or for the establishment, exercise or defence of legal claims; or
- (e) the transfer is necessary in order to protect the vital interests of the data subject; or
- (f) the transfer is made from a register which according to laws or regulations is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate legitimate interest, to the extent that the conditions laid down in law for consultation are fulfilled in the particular case.

2. Without prejudice to paragraph 1, a Member State may authorize a transfer or a set of transfers of personal data to a third country which does not ensure an adequate level of protection within the meaning of Article 25 (2), where the controller adduces adequate safeguards with respect to the protection of the privacy and fundamental rights and freedoms of individuals and as regards the exercise of the corresponding rights; such safeguards may in particular result from appropriate contractual clauses.

3. The Member State shall inform the Commission and the other Member States of the authorizations it grants pursuant to paragraph 2.

If a Member State or the Commission objects on justified grounds involving the protection of the privacy and fundamental rights and freedoms of individuals, the Commission shall take appropriate measures in accordance with the procedure laid down in Article 31 (2).

Member States shall take the necessary measures to comply with the Commission's decision.

4. Where the Commission decides, in accordance with the procedure referred to in Article 31 (2), that certain standard contractual clauses

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offer sufficient safeguards as required by paragraph 2, Member States shall take the necessary measures to comply with the Commission's decision.

CHAPTER V
CODES OF CONDUCT

Article 27

1. The Member States and the Commission shall encourage the drawing up of codes of conduct intended to contribute to the proper implementation of the national provisions adopted by the Member States pursuant to this Directive, taking account of the specific features of the various sectors.

2. Member States shall make provision for trade associations and other bodies representing other categories of controllers which have drawn up draft national codes or which have the intention of amending or extending existing national codes to be able to submit them to the opinion of the national authority.

Member States shall make provision for this authority to ascertain, among other things, whether the drafts submitted to it are in accordance with the national provisions adopted pursuant to this Directive. If it sees fit, the authority shall seek the views of data subjects or their representatives.

3. Draft Community codes, and amendments or extensions to existing Community codes, may be submitted to the Working Party referred to in Article 29. This Working Party shall determine, among other things, whether the drafts submitted to it are in accordance with the national provisions adopted pursuant to this Directive. If it sees fit, the authority shall seek the views of data subjects or their representatives. The Commission may ensure appropriate publicity for the codes which have been approved by the Working Party.

CHAPTER VI
**SUPERVISORY AUTHORITY AND WORKING PARTY ON
THE PROTECTION OF INDIVIDUALS WITH REGARD TO
THE PROCESSING OF PERSONAL DATA**

Article 28

Supervisory authority

1. Each Member State shall provide that one or more public authorities are responsible for monitoring the application within its territory of the provisions adopted by the Member States pursuant to this Directive.

These authorities shall act with complete independence in exercising the functions entrusted to them.

2. Each Member State shall provide that the supervisory authorities are consulted when drawing up administrative measures or regulations relating to the protection of individuals' rights and freedoms with regard to the processing of personal data.

3. Each authority shall in particular be endowed with:

- investigative powers, such as powers of access to data forming the subject-matter of processing operations and powers to collect all the information necessary for the performance of its supervisory duties,
- effective powers of intervention, such as, for example, that of delivering opinions before processing operations are carried out, in accordance with Article 20, and ensuring appropriate publication of such opinions, of ordering the blocking, erasure or destruction of data, of imposing a temporary or definitive ban on processing, of warning or admonishing the controller, or that of referring the matter to national parliaments or other political institutions,

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— the power to engage in legal proceedings where the national provisions adopted pursuant to this Directive have been violated or to bring these violations to the attention of the judicial authorities.

Decisions by the supervisory authority which give rise to complaints may be appealed against through the courts.

4. Each supervisory authority shall hear claims lodged by any person, or by an association representing that person, concerning the protection of his rights and freedoms in regard to the processing of personal data. The person concerned shall be informed of the outcome of the claim.

Each supervisory authority shall, in particular, hear claims for checks on the lawfulness of data processing lodged by any person when the national provisions adopted pursuant to Article 13 of this Directive apply. The person shall at any rate be informed that a check has taken place.

5. Each supervisory authority shall draw up a report on its activities at regular intervals. The report shall be made public.

6. Each supervisory authority is competent, whatever the national law applicable to the processing in question, to exercise, on the territory of its own Member State, the powers conferred on it in accordance with paragraph 3. Each authority may be requested to exercise its powers by an authority of another Member State.

The supervisory authorities shall cooperate with one another to the extent necessary for the performance of their duties, in particular by exchanging all useful information.

7. Member States shall provide that the members and staff of the supervisory authority, even after their employment has ended, are to be subject to a duty of professional secrecy with regard to confidential information to which they have access.

Article 29

Working Party on the Protection of Individuals with regard to the Processing of Personal Data

1. A Working Party on the Protection of Individuals with regard to the Processing of Personal Data, hereinafter referred to as 'the Working Party', is hereby set up.

It shall have advisory status and act independently.

2. The Working Party shall be composed of a representative of the supervisory authority or authorities designated by each Member State and of a representative of the authority or authorities established for the Community institutions and bodies, and of a representative of the Commission.

Each member of the Working Party shall be designated by the institution, authority or authorities which he represents. Where a Member State has designated more than one supervisory authority, they shall nominate a joint representative. The same shall apply to the authorities established for Community institutions and bodies.

3. The Working Party shall take decisions by a simple majority of the representatives of the supervisory authorities.

4. The Working Party shall elect its chairman. The chairman's term of office shall be two years. His appointment shall be renewable.

5. The Working Party's secretariat shall be provided by the Commission.

6. The Working Party shall adopt its own rules of procedure.

7. The Working Party shall consider items placed on its agenda by its chairman, either on his own initiative or at the request of a representative of the supervisory authorities or at the Commission's request.

▼B*Article 30*

1. The Working Party shall:
 - (a) examine any question covering the application of the national measures adopted under this Directive in order to contribute to the uniform application of such measures;
 - (b) give the Commission an opinion on the level of protection in the Community and in third countries;
 - (c) advise the Commission on any proposed amendment of this Directive, on any additional or specific measures to safeguard the rights and freedoms of natural persons with regard to the processing of personal data and on any other proposed Community measures affecting such rights and freedoms;
 - (d) give an opinion on codes of conduct drawn up at Community level.
2. If the Working Party finds that divergences likely to affect the equivalence of protection for persons with regard to the processing of personal data in the Community are arising between the laws or practices of Member States, it shall inform the Commission accordingly.
3. The Working Party may, on its own initiative, make recommendations on all matters relating to the protection of persons with regard to the processing of personal data in the Community.
4. The Working Party's opinions and recommendations shall be forwarded to the Commission and to the committee referred to in Article 31.
5. The Commission shall inform the Working Party of the action it has taken in response to its opinions and recommendations. It shall do so in a report which shall also be forwarded to the European Parliament and the Council. The report shall be made public.
6. The Working Party shall draw up an annual report on the situation regarding the protection of natural persons with regard to the processing of personal data in the Community and in third countries, which it shall transmit to the Commission, the European Parliament and the Council. The report shall be made public.

CHAPTER VII

COMMUNITY IMPLEMENTING MEASURES

▼M1*Article 31*

1. The Commission shall be assisted by a committee.
2. Where reference is made to this Article, Articles 4 and 7 of Decision 1999/468/EC ⁽¹⁾ shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

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FINAL PROVISIONS

Article 32

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive at the latest at the end of a period of three years from the date of its adoption.

⁽¹⁾ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

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When Member States adopt these measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

2. Member States shall ensure that processing already under way on the date the national provisions adopted pursuant to this Directive enter into force, is brought into conformity with these provisions within three years of this date.

By way of derogation from the preceding subparagraph, Member States may provide that the processing of data already held in manual filing systems on the date of entry into force of the national provisions adopted in implementation of this Directive shall be brought into conformity with Articles 6, 7 and 8 of this Directive within 12 years of the date on which it is adopted. Member States shall, however, grant the data subject the right to obtain, at his request and in particular at the time of exercising his right of access, the rectification, erasure or blocking of data which are incomplete, inaccurate or stored in a way incompatible with the legitimate purposes pursued by the controller.

3. By way of derogation from paragraph 2, Member States may provide, subject to suitable safeguards, that data kept for the sole purpose of historical research need not be brought into conformity with Articles 6, 7 and 8 of this Directive.

4. Member States shall communicate to the Commission the text of the provisions of domestic law which they adopt in the field covered by this Directive.

Article 33

The Commission shall report to the Council and the European Parliament at regular intervals, starting not later than three years after the date referred to in Article 32 (1), on the implementation of this Directive, attaching to its report, if necessary, suitable proposals for amendments. The report shall be made public.

The Commission shall examine, in particular, the application of this Directive to the data processing of sound and image data relating to natural persons and shall submit any appropriate proposals which prove to be necessary, taking account of developments in information technology and in the light of the state of progress in the information society.

Article 34

This Directive is addressed to the Member States.

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 4 April 2001

on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products ⁽⁴⁾ requires that applications for authorisation to place a medicinal product on the market should be accompanied by a dossier containing particulars and documents relating to the results of tests and clinical trials carried out on the product. Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products ⁽⁵⁾ lays down uniform rules on the compilation of dossiers including their presentation.
- (2) The accepted basis for the conduct of clinical trials in humans is founded in the protection of human rights and the dignity of the human being with regard to the application of biology and medicine, as for instance reflected in the 1996 version of the Helsinki Declaration. The clinical trial subject's protection is safeguarded through risk assessment based on the results of toxicological experiments prior to any clinical trial, screening by ethics committees and Member States' competent authorities, and rules on the protection of personal data.
- (3) Persons who are incapable of giving legal consent to clinical trials should be given special protection. It is incumbent on the Member States to lay down rules to this effect. Such persons may not be included in clinical trials if the same results can be obtained using persons capable of giving consent. Normally these persons should be included in clinical trials only when there are grounds for expecting that the administering of the medicinal product would be of direct benefit to the patient, thereby outweighing the risks. However, there is a need for clinical trials involving children to improve the treatment available to them. Children represent a vulnerable population with developmental, physiological and psychological differences from adults, which make age- and development- related research important for their benefit. Medicinal products, including vaccines, for children need to be tested scientifically before widespread use. This can only be achieved by ensuring that medicinal products which are likely to be of significant clinical value for children are fully studied. The clinical trials required for this purpose should be carried out under conditions affording the best possible protection for the subjects. Criteria for the protection of children in clinical trials therefore need to be laid down.
- (4) In the case of other persons incapable of giving their consent, such as persons with dementia, psychiatric patients, etc., inclusion in clinical trials in such cases should be on an even more restrictive basis. Medicinal products for trial may be administered to all such individuals only when there are grounds for assuming that the direct benefit to the patient outweighs the risks. Moreover, in such cases the written consent of the patient's legal representative, given in cooperation with the treating doctor, is necessary before participation in any such clinical trial.
- (5) The notion of legal representative refers back to existing national law and consequently may include natural or legal persons, an authority and/or a body provided for by national law.
- (6) In order to achieve optimum protection of health, obsolete or repetitive tests will not be carried out, whether within the Community or in third countries. The harmonisation of technical requirements for the development

⁽¹⁾ OJ C 306, 8.10.1997, p. 9 and

OJ C 161, 8.6.1999, p. 5.

⁽²⁾ OJ C 95, 30.3.1998, p. 1.

⁽³⁾ Opinion of the European Parliament of 17 November 1998 (OJ C 379, 7. 12. 1998, p. 27). Council Common Position of 20 July 2000 (OJ C 300, 20.10.2000, p. 32) and Decision of the European Parliament of 12 December 2000. Council Decision of 26 February 2001.

⁽⁴⁾ OJ 22, 9.2.1965, p. 1/65. Directive as last amended by Council Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

⁽⁵⁾ OJ L 147, 9.6.1975, p. 1. Directive as last amended by Commission Directive 1999/83/EC (OJ L 243, 15.9.1999, p. 9).

- of medicinal products should therefore be pursued through the appropriate fora, in particular the International Conference on Harmonisation.
- (7) For medicinal products falling within the scope of Part A of the Annex to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products⁽¹⁾, which include products intended for gene therapy or cell therapy, prior scientific evaluation by the European Agency for the Evaluation of Medicinal Products (hereinafter referred to as the 'Agency'), assisted by the Committee for Proprietary Medicinal Products, is mandatory before the Commission grants marketing authorisation. In the course of this evaluation, the said Committee may request full details of the results of the clinical trials on which the application for marketing authorisation is based and, consequently, on the manner in which these trials were conducted and the same Committee may go so far as to require the applicant for such authorisation to conduct further clinical trials. Provision must therefore be made to allow the Agency to have full information on the conduct of any clinical trial for such medicinal products.
- (8) A single opinion for each Member State concerned reduces delay in the commencement of a trial without jeopardising the well-being of the people participating in the trial or excluding the possibility of rejecting it in specific sites.
- (9) Information on the content, commencement and termination of a clinical trial should be available to the Member States where the trial takes place and all the other Member States should have access to the same information. A European database bringing together this information should therefore be set up, with due regard for the rules of confidentiality.
- (10) Clinical trials are a complex operation, generally lasting one or more years, usually involving numerous participants and several trial sites, often in different Member States. Member States' current practices diverge considerably on the rules on commencement and conduct of the clinical trials and the requirements for carrying them out vary widely. This therefore results in delays and complications detrimental to effective conduct of such trials in the Community. It is therefore necessary to simplify and harmonise the administrative provisions governing such trials by establishing a clear, transparent procedure and creating conditions conducive to effective coordination of such clinical trials in the Community by the authorities concerned.
- (11) As a rule, authorisation should be implicit, i.e. if there has been a vote in favour by the Ethics Committee and the competent authority has not objected within a given period, it should be possible to begin the clinical trials. In exceptional cases raising especially complex problems, explicit written authorisation should, however, be required.
- (12) The principles of good manufacturing practice should be applied to investigational medicinal products.
- (13) Special provisions should be laid down for the labelling of these products.
- (14) Non-commercial clinical trials conducted by researchers without the participation of the pharmaceuticals industry may be of great benefit to the patients concerned. The Directive should therefore take account of the special position of trials whose planning does not require particular manufacturing or packaging processes, if these trials are carried out with medicinal products with a marketing authorisation within the meaning of Directive 65/65/EEC, manufactured or imported in accordance with the provisions of Directives 75/319/EEC and 91/356/EEC, and on patients with the same characteristics as those covered by the indication specified in this marketing authorisation. Labelling of the investigational medicinal products intended for trials of this nature should be subject to simplified provisions laid down in the good manufacturing practice guidelines on investigational products and in Directive 91/356/EEC.
- (15) The verification of compliance with the standards of good clinical practice and the need to subject data, information and documents to inspection in order to confirm that they have been properly generated, recorded and reported are essential in order to justify the involvement of human subjects in clinical trials.
- (16) The person participating in a trial must consent to the scrutiny of personal information during inspection by competent authorities and properly authorised persons, provided that such personal information is treated as strictly confidential and is not made publicly available.
- (17) This Directive is to apply without prejudice to Directive 95/46/EEC 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⁽²⁾.
- (18) It is also necessary to make provision for the monitoring of adverse reactions occurring in clinical trials using Community surveillance (pharmacovigilance) procedures in order to ensure the immediate cessation of any clinical trial in which there is an unacceptable level of risk.

⁽¹⁾ OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7)

⁽²⁾ OJ L 281, 23.11.1995, p. 31.