



**12178/03/EN
WP 91**

Working Document on Genetic Data

Adopted on 17 March 2004

This Working Party was set up under Article 29 of Directive 95/46/EC. It is an independent European advisory body on data protection and privacy. Its tasks are described in Article 30 of Directive 95/46/EC and Article 14 of Directive 97/66/EC.

The secretariat is provided by Directorate E (Services, Copyright, Industrial Property and Data Protection) of the European Commission, Internal Market Directorate-General, B-1049 Brussels, Belgium, Office No C100-6/136.
Website: www.europa.eu.int/comm/privacy

Working Document on Genetic Data

THE WORKING PARTY ON THE PROTECTION OF INDIVIDUALS WITH REGARD TO THE PROCESSING OF PERSONAL DATA,

Having regard to 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 data¹, and in particular Articles 29 and 30 paragraph 1 (a) thereof,

Having regard to the Rules of Procedure of the Working Party², and in particular Article 12 and 14 thereof,

HAS ADOPTED THE PRESENT WORKING DOCUMENT

I. GENERAL OUTLINE OF THE ISSUES

The technical progress which science has made over recent years in the field of genetic research has given rise to new data protection questions and concerns in relation to the significance and impact of genetic tests and the processing of genetic data.

The sound protection of genetic data can be considered nowadays to be a prerequisite in order to ensure respect for the equality principle as well as to make the right to health a reality. All the most recently published international instruments actually prohibit any discrimination based on genetic data. Under Article 21 of the Charter of Fundamental Rights of the EU, “any discrimination based (...) on genetic features” shall be prohibited, and this prohibition can also be found in the Council of Europe’s Convention on Human Rights and Bio-Medicine (Article 11) and UNESCO’s Universal Declaration on Human Genome and Human Rights (Article 6).

Effectiveness of these prohibitions is related to the existence of strict rules limiting the opportunities for using genetic data. Indeed, the protection of the right to health is conditional upon the assurance that no genetic data may be known to third parties, who might use it to discriminate against and/or stigmatise the data subject. In the USA, there have been many cases in which individuals have decided not to undergo genetic tests – although they were necessary to protect their health – because they feared that the findings might come to be known by their employers and insurance companies. This gave rise to a lively debate as well as to the passing of important legislation. Indeed, in Section 2(5) of the Genetic Information Nondiscrimination Act recently adopted by the US Senate, which is currently before the House of Representatives, it is stressed that a “Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, *thereby allowing individuals to take advantage of genetic testing technology, research, and new therapies*”. Based on this assumption, the Act lays down very strict rules under which genetic information may not be used by either employers or insurance companies.

¹ OJ L 281, 23.11.1995, p. 31, available at:
http://europa.eu.int/comm/internal_market/en/media/dataprot/index.htm

² Adopted by the Working Party at its third meeting held on 11.9.1996.

In its opinion 6/2000 on the Human Genome and Privacy, issued on 13 July 2000, the Working Party already emphasised the necessity of coupling new genetic technologies with adequate safeguards to protect the right for privacy. In their annual international conference in Santiago de Compostela in September 1998, the European Data Protection Authorities expressed their concerns on the creation of a nationwide centralised database of medical records to be used for genetic research in Iceland. They recommended that the Icelandic authorities reconsider the project in the light of the EU Data Protection Directive principles and in particular the importance of securing anonymity and stressed that economic interests should not lead to an extension of the original purpose of the database.

Given the growing importance and sensitivity of the issues related to the protection of the genetic data as well as the initiatives currently in progress both at national and supranational level, the Working Party introduced this topic in its Work Programme for 2003.

At regulatory level the situation across the EU appears to be uneven. Indeed, while some Member States have explicitly listed genetic data as sensitive data in their Data Protection law with all the safeguards and restrictions associated, in most Member States the issue of the processing of genetic data is not as such regulated by specific legislation. However, some Member States do provide for complementary rules in their laws on patient's rights and legal regulations for the processing of genetic data. As national authorities become increasingly aware of the risks associated with the processing of genetic data, a general trend towards new initiatives at the national regulatory level is anticipated.

Furthermore, at the supranational level, the conditions for the performance of genetic tests, which are a prerequisite for the subsequent performance of the processing of the relevant data obtained, have been taken into account and/or are in the process of being dealt with³. The only legally-binding international instrument that exists today remains the Convention on Human rights and Biomedicine adopted in 1997 in Oviedo and opened since then for accession and ratification⁴. The Convention bans all forms of discrimination based on the grounds of a person's genetic profile and allows the carrying out of predictive genetic tests only for medical purposes.

The main purpose of the present document is to identify areas of concern related to the processing of genetic data from a data protection perspective and contribute to a more uniform approach in the light of the national measures adopted in this field under

³ COUNCIL OF EUROPE

- Working Document on the Applications of Genetics for Health Purposes of 7 February 2003, which is currently the subject of consultation, being closely related to the principles laid down in the 1997 Biomedicine Convention.
- Draft Explanatory Report of the Steering Committee on Bioethics (CDBI) to the Draft Additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research of 22 August 2003 has been transmitted to the Parliamentary Assembly which plans to discuss it at the end of January 2004.

UNESCO

- International Declaration on Human Genetic Data of the IBC adopted on 16 October 2003.

⁴ The Chart of signatures and ratifications of the Convention on Human Rights and Biomedicine is published at the following URL address :

<http://conventions.coe.int/Treaty/EN/searchsig.asp?NT=164&CM=1&DF=>

Directive 95/46/EC. Moreover, the Working Party's ambition at this stage is to establish a common understanding of the different issues relating to the processing of genetic data. Third pillar issues related to genetics will not be dealt with in detail by the present document as they do not fall within the scope of the Directive.

II. DEFINITIONS AND MAIN CHARACTERISTICS OF GENETIC DATA

Definitions:

All data of whatever type concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals (*Council of Europe Recommendation N°R(97)5*)

Any data concerning the hereditary characteristics of an individual or group of related individuals (*Art 2 (g) of the 2 August 2002 law of Luxembourg on the protection of persons with regard to the processing of personal data*)

Non-obvious information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis (*International Declaration on Human Genetic data, UNESCO*)

Characteristics:

Genetic data show in themselves characteristics which make them singular, in particular compared to health data. They provide or are likely to provide, in the future, scientific, medical and personal information relevant throughout the life of an individual. This information can also have a significant incidence on the family of the data subject, over several generations and in certain cases on the whole group to which the data subject belongs.

The identification by the genetic print also presents a unique nature. Indeed, genetic data are likely to reveal information on several people while making it possible to identify only one of them. They reveal the uniqueness of the data subject.

As a result of these specificities, the processing of genetic data requires and justifies a particular legal protection. Such is the object pursued by the working paper on genetic data.

But, mankind should not be reduced to its genetic characteristics only, to its sole genetic cartography, which in any case does not constitute the ultimate universal explanation of human life.

One of the first guarantee conditioning the use of genetic data should therefore be to avoid attributing to these data a universal explanatory value.

Genetic data thus present a number of characteristics which can be summarised as follows:

- while genetic information is unique and distinguishes an individual from other individuals, it may also at the same time reveal information about and have implications for that individual's blood relatives (biological family) including those in succeeding and preceding generations, Furthermore, genetic data can characterise a group of persons (e.g. ethnic communities);
genetic data can reveal parentage and family links;

- genetic information is often unknown to the bearer him/herself and does not depend on the bearer's individual will since genetic data are non modifiable;
- genetic data can be easily obtained or be extracted from raw material although this data may at times be of dubious quality;- taking into account the developments in research, genetic data may reveal more information in the future and be used by an ever increasing number of agencies for various purposes.

III. APPLICABILITY OF THE 95/46/EC DIRECTIVE

According to Art 2 (a) of the Directive: *"personal data" shall mean any information relating to an 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.*"

There is no doubt that genetic information content is covered by this definition. Indeed, a link to a specific person, i.e. the fact that the person concerned is identified or identifiable, is clear in the majority of cases. Nevertheless in some cases it is less clear, e.g. samples of DNA taken in a given place, such as traces at the scene of a crime. However, such samples may constitute a source of personal data in so far as it may be possible to associate samples of DNA with a given person, in particular once their origin has been confirmed by a court upon the forensic evidence. Therefore, in regulating genetic data, consideration should also be given to the legal status of DNA samples.

According to Article 8(1) of the Directive, categories of personal data whose sensitivity requires a higher level of protection includes "data concerning health". Genetic data may provide to an extent a detailed picture of a person's physical disposition and health condition and therefore could be considered as "data concerning health". Furthermore, genetic data may also describe specific forms of a wide range of physical characteristics. Thus, genetic data which determine the colour of someone's hair, for example, may not be regarded as data directly concerning health. In this context, genetic data can contribute e.g. to assess the ethnic origin of an individual and should as well be considered as falling within the scope of Art 8 (1).

Considering the extremely singular characteristics of genetic data and their link to information that may reveal the health condition or the ethnic origin, they should be treated as particularly sensitive data within the meaning of Article 8 (1) of the Directive and therefore be subject to the reinforced protection provided for in the Directive and the national laws transposing it.

According to Article 8 (3) of the Directive, the singularity of sensitive data is such that it may only be processed in exceptional circumstances, i.e. : "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 according to specific conditions. Indeed, data concerning health may only be processed by a health professional subject to the obligation of medical secrecy or by another person subject to an equivalent obligation of secrecy. It can be argued that genetic data could be processed in one of the exceptional circumstances listed above.

According to Art 6 of the Directive, personal data must be collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes (Finality principle). In addition, personal data must be adequate, relevant

and not excessive in relation to the purposes for which they are collected and further processed (Proportionality principle).

Considering the complexity and the sensitivity of the genetic information, there is a great risk of misuse and/or re-use for various purposes by the data controller or third parties. Risks of re-use might occur e.g. using the genetic information already extracted, or through additional analysis of the underlying material (e.g. blood sample). The Directive prohibits further processing that would be incompatible with the purpose for which the data was collected. Nevertheless, it provides for exemptions to the prohibition to further process data for historical, statistical or scientific purposes provided that Member States put in place appropriate safeguards.

Furthermore, an evaluation of the respect for proportionality and the respect for legitimacy is necessary, taking into account the risks for the protection of fundamental rights and freedoms of individuals and notably whether or not the intended purpose could be achieved in a less intrusive way. Genetic data may only be used if adequate, relevant and not excessive. This implies a strict assessment of the necessity and proportionality of the processed data. (Example Case: the Spanish Data Protection Authority (DPA) deemed that the creation of a file of genetic samples to identify newborns through DNA testing was not in order. The aim of such files would be to prevent mother-infant mismatches. The Spanish DPA took the view that the creation of a genetic file would contravene the principle of proportionality since the same result could be reliably obtained with other means e.g. identity bracelets or footprints.) Proportionality has been the main criterion in almost all decisions taken until now by the Data Protection Authorities on the processing of genetic data.

The respect of the finality and proportionality principles imply a clear determination of the purpose for which genetic data are collected and further processed. To avoid incompatible re-use it is essential that the purposes for processing genetic data are clearly defined.

According to Article 10 of the Directive, the data subject has a right to receive information from the controller (or his representative) when the data is collected directly from said data subject. **According to Article 11 of the Directive**, the data subject also has a right to receive information from the controller (or his representative) when the data has not been obtained from said data subject. Given the sensitivity of genetic data, the right to information is particularly relevant in the context of the processing of such data. In cases where the exemption provided for under Article 8.3 is applicable, the health professional might be confronted with the following dilemma: on the one hand he could be bound by the obligation of secrecy, while on the other hand he could be obliged under article 11 to provide information to the data subject (e.g.: in the case where information is extracted from genetic material received from relatives).

IV. PURPOSES FOR WHICH THE COLLECTION AND PROCESSING OF GENETIC DATA MAY TAKE PLACE AND RELEVANT ISSUES

Due to the special nature and characteristics of genetic data and the impact their use may have on the individual's life and on the members of his family, it is very important to determine the purposes for which genetic data may be processed.

- **Health care/ medical treatment**

Genetic testing has proved to be a great tool to assess an individual's health. Understanding how genetics influence every aspect of health can lead to far more effective ways to treat, cure or even prevent diseases. Collection of genetic data to enhance health care is deemed the main legitimate purpose for their further processing.

Diagnostic genetic tests serve to clarify the causes of an already clinically manifest illness. Genetic investigation carried out for diagnostic purposes can either take the place of conventional diagnostic instruments or be used to complement them. Diagnostic tests may also have a predictive health component as well, with regard to members of the family of the person concerned.

Predictive genetic tests are designed to identify genetic changes which are highly likely to lead to an illness at a later point in the life of the person tested. A particular problem associated with predictive diagnostics is that, even if genetic changes can be identified which are demonstrably linked to certain illnesses, it often cannot be predicted with certainty if and when a particular illness will occur in the later life of the person concerned.

In both cases, the data subject should be duly informed about the necessity of carrying out such tests and give its **explicit consent** for that purpose and for the processing of its genetic data (Art 8. 2 (a)). **Informed consent** is particularly crucial in the field of genetic testing as the information that individuals will receive about themselves could have serious implications. **Free consent** should mean that an individual is not coerced into undergoing genetic testing and without it being his express will to do so.

Right to know/access to the genetic information by the members of the biological family of the person concerned:

Right to know:

One of the fundamental features of genetic data consists both in its marking out an individual from others and the fact that this data – and more precisely: the characteristics to which it refers - is structurally shared by all the members of the same biological group – whereas other mechanisms by which personal data are shared depend on the data subjects' will, on social custom, or on legal rules.

Since the results of genetic testing may have serious implications/consequences for the members of a biological family, questions on the information to be given to the relatives from a data protection perspective are raised.

In the European Convention on Bio-medicine as well as in the Universal Declaration on Human Genome, the approach to protecting data confidentiality would appear to be based on an individualistic concept. A totally different approach has been followed by other equally significant instruments, which are more mindful of the importance attributed nowadays to genetic data – such as the Council of Europe’s Recommendation No. R(97)5, Clinton’s Executive Order of 8 February 2000 (“To Prohibit Discrimination in Federal Employment Based on Genetic Information”), the Statement on DNA Sampling by the Hugo Ethics Committee, the 2003 International Declaration on Human Genetic Data of UNESCO, and the Genetic Information Non-discrimination Act.⁵

Given the highly sensitive nature of this issue, a balance must be found between a data subject’s right not to disclose his or her genetic information and the potential serious implications/consequences the disclosure and use of such information could have on the members of a biological family.

Indeed, the specificity of genetic data makes it necessary to view some aspects of the regulations applying to them in a more than merely individualistic perspective – with particular regard to access to these data by kindred members inside the relevant biological group. Furthermore, issues related to the mechanisms for circulating genetic information within this group arise. These issues concern, in particular, a possible obligation, for an individual to disclose his/her genetic data to his/her kindred where such data are relevant in view of safeguarding their health, and the exercise of the right not to know inside the group.

In this context, questions arise as to whether or not genetic data belong exclusively to the single, specific individual from whom they are collected, and to whether family members have the right to access to such data even in the absence of the individual’s consent.

To the extent that genetic data has a family dimension, it can be argued that it is “shared” information, with family members having a right to information that may have implications for their own health and future life.

The precise legal consequences of this argument are not clear yet. At least two scenarios can be imagined. One is that other family members could also be considered as “data subjects” with all the rights that follow from this. Another option is that other family members would have a right of information of a different character, based on the fact that their personal interests may be directly affected. However, in both scenarios

⁵ In the Recommendation by the Council of Europe, genetic data are defined as any data of whatever type “concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals”. Under the Executive Order, “protected genetic information” also includes information “about the occurrence of a disease, or medical condition or disorder in family members of the individual” (see Section 2(e)C). The Hugo Ethics Committee recommended that “special consideration should be made for access by immediate relatives”, and actually attached special importance to the relatives’ role by making destruction of collected data conditional upon their lack of interest in accessing such data. In the International Declaration on Human Genetic Data it is pointed out that such information has a “special status” because of its “significant impact on the family”. The Genetic Information Nondiscrimination Act provides that “the term ‘genetic information’ means information about (i) an individual’s genetic tests; (ii) the genetic tests of family members of the individual” (see Section 101(6) and elsewhere).

further options and conditions would have to be considered to accommodate the various conflicts that are likely to arise between the different claims of family members, either to have access to information or to keep it confidential.

A case was addressed in this connection in Italy, in 1999, through a decision issued by the Garante per la protezione dei dati personali, which granted a lady the possibility to access her father's genetic data although the latter had denied his consent. This request was granted by considering that the father's right to privacy was to be overridden by the lady's right to health – the latter meaning her “psychological and physical well-being”.⁶

Thus, a new, legally relevant social group can be said to have come into existence – namely, the biological group, the group of kindred as opposed, technically speaking, to one's family. Indeed, such group does not include family members such as one's spouse or foster children, whereas it also consists of entities outside the family circle – whether in law or factually – such as gamete donors or the woman who, at the time of childbirth, did not recognise her child and requested that her particulars should not be disclosed – this right being supported in certain legal systems. The anonymity granted to the latter entities raises a further issue, which is usually dealt with by providing that the personal data required for genetic testing be communicated exclusively to a physician without referring to the identity of the relevant individual.

Given the complexity of the issues described above, the Working Party takes the view at this stage that consideration should be given to a case by case approach in deciding how to address possible conflicts between the interests of the data subjects and those of their biological family.

Right not to know: It is the case where the person concerned chooses not to be informed of the results of the genetic test nor receive any further information (i.e. as to whether it is carrying a defective gene or is going to suffer a disease) particularly if the disease is highly serious and at the time there are no scientific means to prevent or treat it. The same applies to the family members who may wish to assert a right not to know about the results of a test taken by a family member to determine the presence or absence of a serious genetic disorder, preferring to live their lives without the shadow of such information. This is particularly true when there is no prevention or treatment available.

(Case example: The CNIL came to the conclusion that it was not appropriate to systematically inform the family of patients who carry a gene of an incurable disease and to generate in this way permanent anxiety without a possible direct benefit for the members of the family, as no useful treatment would be available to them in the near future.)

⁶ The lady had requested disclosure of the data to carry out a genetic test and subsequently take a fully informed reproductive decision – upon assessing the risk of transmitting a genetic disease that affected her father. The authorisation granted by the Garante could be reached by taking account of the peculiar features of genetic data, which are transmitted from one generation to the next one and thereby represent the common heritage of several entities; the Council of Europe's Recommendation was expressly referred to in the decision, which was published in the Garante's Bulletin (Cittadini e società dell'informazione 1999, no. 8, p. 13-15).

Counselling: Genetic testing inevitably poses certain ethical and legal questions and informed decision making is very important in this respect. Therefore, extraordinary conditions such as preliminary counselling may apply in certain cases (e.g. counselling to couples that wish to undergo genetic testing before taking the decision to give birth to a child). This aspect, although an important issue, will not be developed in the present paper.

- **Employment**

From the employer's point of view, the processing of genetic data could be used in a pre-recruitment stage in order to help him/her identify candidates that are not fit for a specific job e.g in case of a declared disease or are likely to suffer from diseases and therefore not hire such candidates. From the employee's perspective, genetic tests may provide him/her with information on whether a particular job is suitable for him/her and what protective measures can be taken to improve its workplace.

The Working Party has had the opportunity to examine the processing of genetic data in the employment context on the basis of the consultation document on a "Community framework concerning the protection of worker's personal data in the employment context". In its concluding document, dated 24th of September 2003, the Working Party considered that the processing of genetic data in the field of employment should be prohibited in principle. The Working Party added that the processing of the latter should only be authorised under really exceptional circumstances and by taking also account of the ban against their processing that is already in force in several Member States.

Furthermore, as pointed out in the opinion of July 2003 by the European Group on Ethics in Science and New Technology concerning "Ethical Aspects of Genetic Testing in the Workplace", "there is, up to now, no proven evidence that the existing genetic tests have relevance and reliability in the context of employment. They still have uncertain predictive value". Therefore, it is not to be allowed that individuals may be discriminated against on the basis of information that, in predictive terms, should not be regarded as final in most cases – both because its effects depend on the association with other factors, such as environmental factors, and because of its probabilistic nature

- **Insurance**

The Working Party believes at this stage that the processing of genetic data in the field of insurance should be prohibited in principle and only authorised under really exceptional circumstances, clearly provided for by law. Indeed, the use of genetic data in the insurance field could lead to an insurance applicant or members of his family being discriminated against on the basis of their genetic profile. In some cases insurance applicants might, as a result of an unfavourable finding in a genetic test, be required to pay exorbitant premiums for insurance cover or even be regarded as uninsurable on the basis of a potential illness which may even never arise. This position is in line with the positions adopted in most Member States, where the processing of genetic data in the field of insurance does not constitute a legitimate purpose.

- **Medical and scientific research**

In recent years large volumes of genetic data have been collected and stored for research activities. The main reason for this processing is to advance the understanding of the human genome and its potential in medicine, following the work of genetic scientists with regard to DNA. Research databases or the so-called bio-banks have proved to make an important contribution to health care.

The establishment of large genetic research databases is, however, a potential cause of concern from a data protection perspective. Issues such as a) the further processing of the data for purposes that may have not even been conceived at the time of their collection b) the duration of storage of genetic data, and c) the appropriate security measures, should be thoroughly examined.

Bio banks are an ongoing study. Once established, such databases are potentially subject to a number of different uses or appetites. In fact, many of the research uses are secondary to some of the original purposes. Given the potential financial ramifications linked to scientific research on genetics, it is currently unrealistic to predict how fast this research will develop.

In this respect the issue of prescribing practices applying anonymisation could be a possibility to address issues from the data protection perspective.

Nevertheless, it seems that during a certain period and for the research purpose, the person carrying out the research needs to be able to link the data with the data subject (e.g. to assess the evolution of a sickness, the reaction to a treatment etc.). In addition, there has been evidence that stored DNA is capable of being linked to a particular person - provided certain additional knowledge is available, even though it may not be stored in a directly person-specific way. According to a definition of the task group established by the Danish government to assess the need for further legislative proposals in Denmark, *a bio-bank is defined as a structured collection of human biological material which is accessible under certain criteria and where information contained in the biological material can be traced back to individuals.*

The question on the duration of storage of genetic data is also linked to the feasibility of the anonymisation process. Usually, after some years, identifiable characteristics can be stripped from the research data base and thus the data become anonymous and irretrievably unlinked to an identifiable person. In France, for example, the "Huriet" Act of 20/12/1988 on clinical trials provides that data cannot be anonymised before 15 years after their collection. The Dutch data protection authority has been confronted with situations where anonymisation or deletion of data kept in biobanks could substantially diminish the value and functions of such data bases, since the data would no longer be linked to identifiable individuals. Examples are databases for longitudinal researches, sometimes encompassing several generations, such as the cancer registration. Arguments from the field for longer retention periods should be taken into account in such cases.

Another issue is the security measures employed to protect the data used for medical and scientific research purposes. Concerning the use of bio banks, high level security measures, both organisational and technical, should be taken to protect the data contained therein, in compliance with Article 17 of the Directive. For instance, data controllers should be encouraged to carry out surveys of potential risks, establish policies for

security, inform and train staff on an on-going basis, set up restricted access controls in order to avoid undue access by administrative staff and other persons, etc.

- **Identification**

Genetic data has proved to be an important tool in the process of identification in various fields. The most important to mention would be to aid criminal investigations aimed at identifying offenders as well as to enhance the identification of missing persons . In this latter case the processing performed, while undertaken without the consent of the missing data subject, would be justified on the grounds of the existence of circumstances of vital interest to the individual concerned. As far as the criminal investigations are concerned, according to the penal law of some Member States the consent of the individual suspected of having committed an offence is not a prerequisite for the processing of its genetic data. From a data protection perspective the most important area where genetics can be used for identification purposes is to test the existence of paternal or other family links. In most of the cases such testing is decided by the Court during a civil suit and the explicit consent of the parties involved is required.

However, there is a proliferation of Internet-based offers of genetic tests aimed especially at establishing fatherhood. It is a new emerging technology known as 'genetic testing direct to the public' or 'genetic home testing'. This kind of test allows an individual to determine the paternity of a child, for example, by sending samples from the relevant individuals by post to a testing laboratory to undergo analysis. This results in a determination as to whether the 'father' is the genetic father of the child. Such services are advertised on the Internet and the necessary samples can be obtained covertly, for example by taking a sample of hair from a pillow. The covert nature of the sampling could mean that an individual is in effect subject to genetic testing without any knowledge of the testing and consequently without his or her consent.

In this respect, the ease with which genetic material can be obtained without the data subject's knowledge (and therefore consent) and further used with a view to carrying out paternity tests must be prevented by a clear rule, as is the case in several Member States. Moreover, exemptions in this field should specifically safeguard the data subject's interests/rights. For instance, the Dutch DPA has decided that each individual involved in genetic testing should sign a declaration stating that the collected DNA samples belong to itself and that it consents to participate in the test. With regard to minors, the Dutch DPA stated that a written declaration should be produced by their legal representatives. In their written declaration, each representative should stipulate that he/she consents to the child's participation and assert that the DNA samples belong to the child. Finally, the concerned representative should indicate whether there are other legal representatives, and if so, he/she should declare that they do not object to the genetic testing.

V. CONCLUSIVE REMARKS

Given the fast moving age of technological, scientific and economic developments in the field of genetics and taking into account the variety of purposes for which the processing of genetic data may take place, the Working Party felt it was necessary at this stage to define a common approach with a view to establishing the appropriate safeguards for the processing of genetic data. The main lines of this approach can be summarised as follows:

- Any use of genetic data for purposes other than directly safeguarding the data subject's health and pursuing scientific research should require national rules to be implemented, in accordance with the data protection principles provided for in the Directive, and in particular the finality and proportionality principles. The application of these principles render the blanket implementation of mass genetic screening unlawful.

Furthermore, in accordance with these principles, the processing of genetic data should be authorised in the employment and insurance fields only in very exceptional cases provided for by law, so as to protect individuals from being discriminated against on the basis of their genetic profile.

In addition, the ease with which genetic material can be obtained unbeknownst to the data subject and the relevant information can be subsequently extracted from such material, requires strict regulations in order to prevent the dangers related to new forms of "identity theft" – which would be especially dangerous in this sector and might affect fatherhood and motherhood, or even the possibility of using the material for cloning purposes. This is why, in regulating genetic data, one should not fail to consider the legal status of the DNA samples used for obtaining the information at stake. Among the issues addressed, special importance should be attached to the application of a wide range of data subjects' rights to the management of such samples, as well as to destruction and/or anonymisation of the samples after obtaining the required information.

Finally, procedures should be put in place in order to ensure that genetic data are only processed under the supervision of qualified professionals who are entitled to such processing on the basis of specific authorisations and rules.

- In Member States where the purposes and the appropriate safeguards for the processing of genetic data are not established by law, the DPAs are encouraged to play an even more active role in ensuring that the finality and proportionality principles of the Directive are fully respected.

In this respect, the Working Party recommends that Member States should consider submitting the processing of genetic data to prior checking by DPAs, in accordance with Article 20 of the Directive. This should in particular be the case with regard to the setting up and use of bio banks.

Moreover, closer cooperation and exchange of best practices between DPAs could prove to be an efficient way to compensate the present absence of

regulatory framework in the field of the on-line "genetic testing direct to the public".

- It is worth noting that a new, legally relevant social group is coming into existence – namely, the biological group, the group of kindred as opposed, technically speaking, to one's family. Indeed, such a group does not only include family members such as one's spouse or foster children, but it can also consist of entities outside this family circle – whether in law or factually (e.g. : gamete donors).

The Working Party intends to revisit this working document in the light of the experience acquired by the data protection authorities with regard to the processing of genetic data. This document should be regarded as a stepping stone towards further discussions on the issues at stake. The Working Party will closely monitor the evolution of said issues and may decide to focus in detail on specific areas at a later stage, in order to keep in line with the technological developments linked to the processing of genetic data.

Done at Brussels, on 17th March 2004

For the Working Party
The Chairman
Peter Schar