



32 C/29
28 August 2003
Original: French/English

Item 8.7 of the provisional agenda

**DRAFT INTERNATIONAL DECLARATION
ON HUMAN GENETIC DATA**

OUTLINE

Source: 165 EX/Decision 3.4.2.

Background: Under the terms of the said decision, the Director-General was invited to submit to the General Conference at its 32nd session, the draft international declaration on human genetic data.

Purpose: This document reviews the main stages in the preparation of the draft international declaration on human genetic data, which is contained in section III. The document contains, in an annex, the report of the Meeting of Government Experts convened by the Director-General pursuant to the relevant decisions of the Executive Board, and also the list of States and organizations represented at the meeting.

An addendum to this document will contain the outcome of the Executive Board's consideration of the draft declaration at its 167th session (item 5.3) and its decision on the subject.

I. INTRODUCTION

1. At its 31st session (October-November 2001), the General Conference endorsed the Director-General's proposal to begin work on the preparation of an international instrument on genetic data, and requested him "to keep it informed of the action which he intends to take on the advice and recommendations of IBC and IGBC concerning the possibility of drafting an international instrument on genetic data" (31 C/Resolution 22, para. 5).
2. The purpose of this document is to outline the stages leading up to the drafting of the draft international declaration on human genetic data, which is contained in section III.

II. PREPARATION OF THE DRAFT INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

3. At the Round Table of Ministers of Science on "Bioethics: International Implications" convened by the Director-General on 22 and 23 October 2001, participants took the view that possible extensions to the Universal Declaration on the Human Genome and Human Rights should be considered (para. 7(i) of the Communiqué).
4. In fact, the International Bioethics Committee (IBC) has been looking into the question of genetic data since 1999, with the preparation of a report on "Confidentiality and genetic data", followed by a document entitled "Human genetic data: preliminary study by the IBC on its collection, treatment, storage and use", finalized in 2002.
5. Immediately after the 31st session of the General Conference, at the request of the Director-General, IBC set up an ad hoc Drafting Group, co-chaired by Ms Nicole Questiaux (France) and Judge Patrick Robinson (Jamaica), to make proposals on the form and content of an international instrument on genetic data. At its first three meetings (February, April and July 2002), the Drafting Group came out clearly in favour of a non-binding instrument, opting from the outset for a declaration, the preparation of which would be not only a logical sequel to the Universal Declaration on the Human Genome and Human Rights (1997), but also a means for its implementation.
6. At its 165th session in October 2002, the Executive Board, after examining the work of IBC, stated that it was: "Aware at once of the complexity and the scope of the issue of genetic data and also of the urgent need to define in this regard principles and standards that are recognized and adopted at the international level". It therefore considered that "the Organization should prepare, as a matter of urgency, an international declaration on human genetic data with due regard for human dignity and human rights and freedoms" (165 EX/Decision 3.4.2).
7. Acting on the terms of reference entrusted to it by the Executive Board, the IBC Drafting Group proceeded with the drafting of a preliminary outline of the international declaration on human genetic data, which was examined by IBC in a public meeting at its ninth session (Montreal, 26-28 November 2002).
8. A Revised Outline, finalized by the Drafting Group in January 2003, was subsequently the subject of a broad international written consultation among all UNESCO Member States and Associate Members, relevant international intergovernmental and non-governmental agencies and national bodies, and also among some 150 specialists and eminent personalities and a number of

representatives of the private sector.¹ In addition, IBC organized a day of public hearings on human genetic data and the Revised Outline of the declaration (Principality of Monaco, 28 February 2003), which ensured the involvement of various stakeholders particularly concerned by the future declaration (indigenous peoples, women, children, disabled persons, patients, doctors and researchers, the private sector and insurance companies), the results of which were taken into account by the Drafting Group at its fifth meeting (1 and 2 March 2003).

9. At its 166th session in April 2003, after having taken note of the work carried out by IBC, particularly its Drafting Group, the Executive Board invited the Director-General to take account of the results of the international consultation and “to submit a consolidated text, taking account of the results of the international consultation, including the advice of the IBC at its May 2003 meeting, to the meeting of government experts (Category II) responsible for finalizing the draft international declaration on human genetic data (Paris, 25-27 June 2003) ... with a view to its adoption by the General Conference at its 32nd session” (166 EX/Decision 6.2).

10. At the request of the Director General, the Chairperson of IBC, Ms Michèle S. Jean (Canada), the Co-Chairpersons of the Drafting Group and its Rapporteur, Mr Georges B. Kutukdjian (Lebanon), in consultation with the Drafting Group as a whole, accordingly undertook the revision of the text of the future declaration and finalized a provisional preliminary draft of the international declaration on human genetic data (23 April 2003) which took account of the comments made at the day of public hearings, observations made at the 166th session of the Executive Board of UNESCO, and the replies received in connection with the international written consultation.

11. IBC considered this provisional preliminary draft at its tenth session (Paris, 12-14 May 2003) and, on the basis of the discussions at the session, the Drafting Group, at its sixth meeting (15 May 2003) agreed on the final amendments to be made to the text of the declaration and entrusted the Chairperson of IBC, the Co-Chairpersons of the Drafting Group and the Rapporteur with the task of finalizing the text of the preliminary draft declaration (26 May 2003).

12. For its part, the Intergovernmental Bioethics Committee (IGBC) took up the question of human genetic data at its third session (Paris, 23-24 June 2003) and decided that “Having been informed of the decision of the Executive Board to convene in Paris, immediately after the third session of IGBC, a Meeting of Government Experts Responsible for Finalizing the Draft of the International Declaration on Human Genetic Data with a view to its adoption by the 32nd session of the General Conference, leaves it to this meeting to finalize the said draft” (para. 17 of the Recommendations).

13. The draft international declaration on human genetic data contained in section III was finalized by the Meeting of Government Experts which the Director-General convened at UNESCO Headquarters from 25 to 27 June 2003 pursuant to 165 EX/Decision 3.4.2, 166 EX/Decision 3.3.2 and 166 EX/Decision 6.2 (see the report of the meeting and the list of participants in the annex). The meeting did not, however, wish to give a final opinion on the extent to which the future declaration should apply to forensic medicine and civil and criminal proceedings. The draft declaration therefore shows the relevant provisions (seventh preambular paragraph, Articles 5, 17 and 22) in square brackets. At its 167th session, the Executive Board will be called upon to consider the draft declaration and take a decision on that matter. An addendum to this document will report on the outcome and its decision in that regard.

¹ The results of the consultation are set out in the document entitled “Summary of the International Consultation on the Revised Outline of the International Declaration on Human Genetic Data” (22 January 2003) (SHS/EST/03/CONF.203/5), available from the Division of Ethics of Science and Technology and on the Internet (www.unesco.org/bioethics).

III. DRAFT INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

The General Conference,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the two International United Nations Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the International United Nations Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination Against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Economic and Social Council Resolution 2001/39 on Genetic Privacy and Non-Discrimination of 26 July 2001,² the ILO Convention (No. 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the other international human rights instruments adopted by the United Nations and the specialized agencies of the United Nations system,

Recalling more particularly the Universal Declaration on the Human Genome and Human Rights which it adopted, unanimously and by acclamation, on 11 November 1997 and which was endorsed by the United Nations General Assembly on 9 December 1998, and the Guidelines for the implementation of the Universal Declaration on the Human Genome and Human Rights which it endorsed on 16 November 1999 by 30 C/Resolution 23,

Welcoming the broad public interest worldwide in the Universal Declaration on the Human Genome and Human Rights, the firm support it has received from the international community and its impact in Member States drawing upon it for their legislation, regulations, norms and standards, and ethical codes of conduct and guidelines,

Bearing in mind the international and regional instruments, national laws, regulations and ethical texts relating to the protection of human rights and fundamental freedoms and to respect for human dignity as regards the collection, processing, use and storage of scientific data, as well as of medical data and personal data,

Recognizing that human genetic data have a special status on account of their sensitive nature since they can be predictive of genetic predispositions concerning individuals and that the power of predictability can be stronger than assessed at the time of deriving the data; they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group; they may contain information the significance of which is not necessarily known at the time of the collection of biological samples; and they may have cultural significance for persons or groups,

Considering that the growing amount of personal data collected makes genuine irretrievability increasingly difficult,

Considering that the collection, processing, use and storage of human genetic data are of paramount importance for the progress of life sciences and medicine, for their applications, and for the use of such data for non-medical purposes **[in particular, civil and criminal proceedings and other legal proceedings]**,

² The reference to the resolution likely to be adopted by the United Nations Economic and Social Council in July 2003 will be included in due course.

Aware nevertheless that the collection, processing, use and storage of human genetic data have potential risks for the exercise and observance of human rights and fundamental freedoms, and respect for human dignity,

Reaffirming the principles established in the Universal Declaration on the Human Genome and Human Rights and the principles of equality, justice, solidarity and responsibility as well as respect for human dignity, human rights and fundamental freedoms, particularly freedom of thought and expression, including freedom of research and privacy and security of person, which must underlie the collection, processing, use and storage of human genetic data,

Proclaims the principles that follow and adopts the present Declaration.

A. GENERAL PROVISIONS

Article 1: Aims and scope

(a) The aims of this Declaration are: to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data and of the biological samples from which they are derived, in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research; to set out the principles which should guide States in the formulation of their legislation and their policies on these issues; and to form the basis for guidelines of good practices in these areas for concerned institutions and individuals.

(b) This Declaration applies to human genetic data and, where applicable, to proteomic data and to the biological samples from which they are derived.

Article 2: Use of terms

For the purposes of this Declaration, the terms used have the following meanings:

- (i) *Human genetic data*: Non-obvious information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis.
- (ii) *Consent*: An act by which a person gives his or her agreement to participate in a research study or a procedure.
- (iii) *Biological samples*: Any sample of biological material (for example blood, skin and bone cells or blood plasma) in which nucleic acids are present and which contains the characteristic genetic make-up of an individual.
- (iv) *Population-based genetic study*: A study which aims at understanding the nature and extent of genetic variation among individuals within a group and/or between individuals across different groups.
- (v) *Behavioural genetic study*: A study that aims at establishing possible connections between genetic characteristics and behaviour.
- (vi) *Invasive procedure*: Biological sampling using a method involving intrusion into the human body, such as obtaining a blood sample by using a needle and syringe.
- (vii) *Non-invasive procedure*: Biological sampling using a method which does not involve intrusion into the human body, such as oral smears.

- (viii) *Data linked to an identifiable person*: Data that contain information, such as name, birth date and address, by which the person from whom the data were derived can be identified.
- (ix) *Data unlinked to an identifiable person*: Data that are not linked to an identifiable person, through the replacement of all information about that person with a code.
- (x) *Data irretrievably unlinked to an identifiable person*: Data that cannot be linked to an identifiable person, through destruction of all information about the person who provided the sample.
- (xi) *Genetic testing*: A diagnostic procedure aimed at detecting a genetic pathology or genetic characteristics that predispose a person to a pathology, or a genetic mutation that could be transmitted to descendants.
- (xii) *Genetic screening*: Large-scale systematic genetic testing offered in a programme to a population or subsection thereof intended to detect genetic characteristics in asymptomatic people.
- (xiii) *Genetic counselling*: A procedure to explain the possible implications of the findings of genetic testing or screening, its advantages and risks and where applicable to assist the individual in the long-term handling of the consequences. It takes place before and after genetic testing and screening.
- (xiv) *Cross-matching*: Matching of information about an individual or a group contained in various data files set up for different purposes.

Article 3: Person's identity

Each individual has a characteristic genetic make-up. Nevertheless, a person's identity should not be reduced to genetic characteristics, since it involves complex educational, environmental and personal factors and emotional, social, spiritual and cultural bonds with others and implies a dimension of freedom.

Article 4: Special status

- (a) Human genetic data have a special status because:
 - (i) they can be predictive of genetic predispositions concerning individuals;
 - (ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs;
 - (iii) they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples;
 - (iv) they may have cultural significance for persons or groups.
- (b) Due consideration should be given, and where appropriate special protection should be afforded to human genetic data and to the biological samples.

Article 5: Purposes

Human genetic data may be collected, processed, used and stored for the purposes of:

- (i) diagnosis and health care, including screening and predictive testing;
- (ii) medical and other scientific research, including population-based genetic studies and epidemiological, anthropological or archaeological studies, collectively referred to hereinafter as “medical and scientific research”;
- (iii) **[forensic medicine and civil, criminal and other legal proceedings, according to national legislation;]**
- (iv) or any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights and the international law of human rights.

Article 6: Procedures

(a) It is ethically imperative that human genetic data be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures. States should endeavour to involve society at large in the decision-making process concerning the collection, processing, use and storage of human genetic data and the evaluation of their management, in particular in the case of large-scale population-based genetic studies. This decision-making process, which may benefit from international experience, should ensure the free expression of various viewpoints.

(b) Independent, multidisciplinary and pluralist ethics committees should be established, in accordance with the provisions of Article 16 of the Universal Declaration on the Human Genome and Human Rights. Where appropriate, ethics committees at national level shall be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data and of biological samples. They should also be consulted concerning matters where there is no national legislation. Ethics committees at institutional or local levels should be consulted with regard to their application to specific research projects.

(c) Where two or more States are involved in the collection, processing, use and storage of human genetic data and of biological samples, the ethics committees in the States concerned, where appropriate, should be consulted and the review of these questions at the appropriate level should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.

(d) It is ethically imperative that clear, balanced and comprehensive information shall be provided to the person whose prior, free, informed and express consent is sought without inducement, and that such information shall specify the purpose for which human genetic data are being derived from biological samples, and are used and stored. This information should indicate, if necessary, risks and consequences. This information should also indicate that the person concerned can withdraw his or her consent, without coercion, and which should entail neither a disadvantage nor a penalty for the person concerned.

Article 7: Non-discrimination and non-stigmatization

(a) Every effort should be made to ensure that human genetic data are not used for purposes that are discriminatory or in any way that would lead to the stigmatization of an individual, a family, or a group.

(b) In this regard, appropriate attention should be paid to the findings of population-based genetic studies and behavioural genetic studies and their interpretations.

B. COLLECTION

Article 8: Consent

(a) Prior, free, informed and express consent should be obtained for the collection of human genetic data, either through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions. Limitations on this principle of consent should only be prescribed for compelling reasons by national law or regulation, consistent with the international law of human rights.

(b) When a person is incapable of giving informed consent for genetic testing, authorization should be obtained from the legal representative, in accordance with domestic law.

(c) In the case of children and incapacitated adults they will be consulted, inasmuch as they can understand the issues involved.

(d) In diagnosis and health care, genetic screening and testing of children will normally only be ethically acceptable when it has important implications for the health of the child and has regard to the best interest of the child.

(e) This article does not apply where human genetic data are only collected and used for identification purposes in connection with law enforcement investigations and prosecutions, according to the national or domestic legislation.

Article 9: Withdrawal of consent

When human genetic data and biological samples are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. In accordance with the provisions of Article 6(d), withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned. In case of withdrawal of consent, the data as well as the biological samples should either be returned to the person concerned or destroyed based on his or her decision or, in accordance with the provisions of Article 21(a), saved but irretrievably unlinked from the person concerned, unless national law or regulation makes such provision for their preservation as necessary in the public interest and/or for medico-legal purposes.

Article 10: The right to decide whether or not to be informed about research results

When human genetic data are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This should not apply to research on data irretrievably unlinked to identifiable persons and which do not lead to individual findings concerning the persons who have participated in such a research. Where appropriate, the right not to be informed should be extended to relatives who may be affected by the results.

Article 11: Genetic counselling

It is ethically imperative that when human genetic data are collected for diagnostic and health care purposes or for medical and scientific research purposes, genetic counselling be offered in an

appropriate manner and at all stages of genetic testing and screening. Genetic counselling should be non-directive, culturally adapted and consistent with the best interest of the person concerned.

Article 12: Collection of biological samples for forensic medicine or in civil, criminal and other legal proceedings

When human genetic data are collected for the purposes of forensic medicine or in civil, criminal and other legal proceedings, including parentage testing, requests for the collection of biological samples, *in vivo* or post-mortem, should be made only in accordance with national legislation or regulation, consistent with the international law of human rights.

C. PROCESSING

Article 13: Access

No one should be denied access to his or her genetic data unless such data are irretrievably unlinked from that person as the identifiable source or unless national legislation limits such access in the interest of public health, public order or national security.

Article 14: Confidentiality

(a) States should endeavour to protect the confidentiality of human genetic data linked to an identifiable person, a family or, where appropriate, a group in accordance with national law or regulation and in conformity with the international law of human rights.

(b) Human genetic data linked to an identifiable person shall not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except in cases provided for by national legislation or regulations or where the consent of the person concerned has been obtained provided that such consent is in compliance with national legislation or regulation and the international law of human rights. An individual's participation in studies utilizing genetic data should be regarded as confidential.

(c) Human genetic data collected for medical and scientific research purposes, if justified by the needs of the research, can remain linked to an identifiable person, provided that the confidentiality of the data concerned is guaranteed.

(d) Human genetic data collected for the purposes of scientific research should normally be unlinked to an identifiable person. Even when such data are unlinked to an identifiable person, the necessary precautions shall be taken to ensure the security of the data.

Article 15: Accuracy, reliability, quality and security

The persons and entities responsible for the processing of human genetic data should take the necessary measures to ensure the accuracy, reliability, quality and security of the human genetic data and processing of biological samples. They should exercise rigour, caution, honesty and integrity in the processing and interpretation of human genetic data, in view of their ethical, legal and social implications.

D. USE

Article 16: Change of purpose or of medical and scientific research objective

(a) Human genetic data and the biological samples collected for one of the purposes set out in Article 5 or a given medical and scientific research objective should not be used for a different purpose that is incompatible with the original consent, unless the prior, free, informed and express consent of the person concerned is obtained according to the provisions of Article 8(a) or it is decided by national legislation or regulation that the use proposed is in the public interest and is consistent with the international law of human rights. If the person concerned lacks the capacity to consent, the provisions of Article 8(b) and (c) should apply *mutatis mutandis*.

(b) Whenever the prior, free, informed and express consent cannot be obtained or in the case of data unlinked to an identifiable person, human genetic data may be used in accordance with national legislation or regulations or in accordance with the provisions of Article 6(b).

Article 17: Stored biological samples

(a) Stored biological samples may be used to produce human genetic data with the prior, free, informed and express consent of the person concerned. However, national legislation or regulation may provide that if such data have significance for medical and scientific research or public health purposes, they may be used for those purposes, following the consultation procedures set out in Article 6(b), or after consultation of the competent organ in the State concerned or in accordance with national legislation or regulations, even in the absence of consent of the person concerned or in the case of deceased persons.

(b) The provisions of Article 12 should apply *mutatis mutandis* to stored biological samples used to produce human genetic data for forensic medicine **[or in civil and criminal proceedings or other legal proceedings]**.

Article 18: Circulation and international cooperation

(a) States should regulate, in accordance with their national legislation or regulation and international agreements, the cross-border flow of human genetic data and of the biological samples, so as to foster international medical and scientific cooperation and ensure fair access to this data. Such a system should seek to ensure that the receiving party provides adequate protection in accordance with the principles set out in this Declaration.

(b) Researchers should endeavour to establish cooperative relationships, based on mutual respect with regard to scientific and ethical matters and, subject to the provisions of Article 14, should encourage the free circulation of human genetic data, in order to foster the sharing of scientific knowledge, provided that the principles set out in this Declaration are observed by the parties concerned. Towards this goal, they should also endeavour to publish in due course the results of their research.

Article 19: Sharing of benefits

(a) Consistent with national legislation, benefits resulting from the use of human genetic data collected for medical and scientific research should be shared with society as a whole and the international community. Consistent with national legislation, in case of any commercial benefits accruing to the investigator, the donor of the biological material/data should share this benefit befittingly in accordance with any relevant international agreement. In giving effect to these principles, benefits may take any of the following forms:

- (i) special assistance to the persons and groups that have taken part in the research;
 - (ii) access to medical care;
 - (iii) provision of facilities for new treatments or drugs stemming from the research;
 - (iv) support for health services;
 - (v) capacity-building facilities for research purposes;
 - (vi) development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems;
 - (vii) any other form consistent with the principles set out in this Declaration.
- (b) Limitations in this respect could be provided by national legislation or regulation.

E. STORAGE

Article 20: Monitoring and management framework

States may consider establishing a framework for the monitoring and management of human genetic data, based on the principles of independence, multidisciplinary, pluralism and transparency as well as the principles set out in this Declaration. This framework could also deal with the nature and purposes of the storage of these data.

Article 21: Destruction

(a) If the person concerned so requests, his or her genetic data and the biological samples collected for diagnostic and health care purposes and for medical and research purposes should be destroyed when they are no longer necessary, unless such data are irretrievably unlinked to the person concerned or a national law or regulation makes such provision for their preservation as necessary in the public interest and/or for medico-legal purposes.

(b) [Human genetic data and the biological samples collected from a suspect in the course of a criminal investigation should be destroyed when they are no longer necessary or otherwise provided for by national legislation.]

(c) Human genetic data and the biological samples should be available for forensic purposes and civil proceedings only for as long as they are required for those proceedings.]

Article 22: Crossmatching

Consent should be essential for crossmatching of human genetic data stored for diagnostic and health care purposes and for medical and other scientific research purposes, unless otherwise provided for by national legislation or regulation for compelling reasons and consistent with the international law of human rights.

F. PROMOTION AND IMPLEMENTATION

Article 23: Implementation

(a) States should make every effort to adopt measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with the international law of human rights. Such measures should be supported by action in the sphere of education, training and public information.

(b) In the framework of international cooperation, States should endeavour to enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing of scientific knowledge concerning human genetic data and of the related know-how.

Article 24: Ethics education, training and information

In order to promote the principles set out in this Declaration, States should endeavour to foster all forms of ethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about human genetic data. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large. In this regard, States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 25: Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out therein. On a collaborative basis, the two Committees should be responsible for its monitoring and for the evaluation of its implementation, *inter alia*, on the basis of reports provided by States. The two Committees should be responsible in particular for the formulation of any opinion or proposal likely to further the effectiveness of this Declaration. They should make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference.

Article 26: Follow-up action by UNESCO

UNESCO shall take appropriate action to follow up this Declaration so as to foster progress of life sciences and their applications through technologies, based on the respect of human dignity and the exercise and observance of human rights and fundamental freedoms.

Article 27: Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity, including, in particular, the principles set out in this Declaration.

ANNEX A

FINAL REPORT OF THE MEETING OF GOVERNMENT EXPERTS RESPONSIBLE FOR FINALIZING THE DRAFT INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

I. INTRODUCTION

1. Convened pursuant to 166 EX/Decision 3.4.2 and 6.2 and to 165 EX/Decision 3.3.2 adopted by the Executive Board at its 166th and 165th sessions respectively, the Meeting of Government Experts Responsible for Finalizing the Draft International Declaration on Human Genetic Data met from 25 to 27 June 2003 at UNESCO Headquarters in Paris.

2. Experts representing the governments of the following 57 Member States took part, with the right to vote, in the Meeting's work: Algeria, Argentina, Austria, Azerbaijan, Belgium, Brazil, Canada, Chile, Columbia, Costa Rica, Côte d'Ivoire, Czech Republic, Egypt, El Salvador, Finland, France, Germany, Greece, Iceland, India, Indonesia, Italy, Japan, Korea (Republic of), Kuwait, Latvia, Libyan Arab Jamahiriya, Lithuania, Luxembourg, Madagascar, Malaysia, Mexico, Morocco, Pakistan, Peru, Philippines, Poland, Portugal, the Netherlands, Saudi Arabia, Senegal, Serbia and Montenegro, Spain, Sudan, Swaziland, Switzerland, Tanzania (United Republic of), Togo, Tunisia, Turkey, Ukraine, United Arab Emirates, United Kingdom, Uruguay, Uzbekistan (Republic of), Venezuela and Yemen.

3. The Holy See, Palestine and the United States of America were represented by observers. The World Health Organization (WHO) sent a representative and the following other intergovernmental organizations were represented by observers: the Arab League Educational, Cultural and Scientific Organization (ALECSO), the Council of Europe, the Islamic Educational, Scientific and Cultural Organization (ISESCO) and the Organisation for Economic Co-operation and Development (OECD). The following international non-governmental organizations were also represented by observers: the European Academy of Arts, Sciences and Humanities, the World Academy of Biomedical Technologies (WABT) and the World Federation of Scientific Workers (WFSW). Finally, the following resource persons attended the Meeting: Ms Michèle S. Jean, Chairperson of the International Bioethics Committee (IBC), Ms Nicole Questiaux, Co-Chairperson of the IBC Drafting Group, and Mr Georges Kutukdjian, Rapporteur of the IBC Drafting Group. The list of participants (SHS/EST/03/CONF.203/INF.2).

4. The Meeting was opened by Mr Koïchiro Matsuura, Director-General of UNESCO, who welcomed the participants and observers and provided background on the meeting. The Director-General underlined that the future international declaration on human genetic data, to be adopted by the General Conference at its 32nd session, is an extension of and means of implementing the Universal Declaration on the Human Genome and Human Rights (1997). With an increasing number of genetic data banks and genetic censuses generating calls for international standards and principles on genetic data in order to ensure protection of fundamental freedoms and human dignity, UNESCO undertook as a matter of urgency to elaborate the Preliminary Draft of the International Declaration on Human Genetic Data (26 May 2003) (SHS/EST/03/CONF.203/3) in less than two years. The Director-General stressed that the preliminary draft, supported by two previous IBC reports on the issue of genetic data, is the result of much reflection, examination, notably by the IBC at its Ninth and Tenth Sessions and by the Executive Board at its 166th session, and consultation, via a broad written consultation and a Public Hearings Day conducted in early 2003. In conclusion, the Director-General said that the adoption by the General Conference of the

Universal Declaration on the Human Genome and Human Rights in 1997 speaks to the spirit of the international community in this field and favours the adoption of the new instrument.

5. The Meeting elected by consensus its Chairperson, Mr Fayçal Hentati (Tunisia), Head of Service of the Neurological Institute of Tunisia, and adopted the Agenda (SHS/EST/03/CONF.203/1). On the proposal of Germany, Rule 12.1 of the Rules of Procedure (SHS/EST/03/CONF.203/2) was so as to read that “proposals and amendments shall *in principle* be transmitted in writing to the Secretariat of the Meeting, which shall circulate them to all the chief participants” (amendment indicated in italics). The Meeting then adopted the Rules of Procedure.

6. In accordance with Rule 4 of the Rules of Procedure, the Meeting then elected the members of its Bureau as follows:

Chairperson:	Mr Fayçal Hentati (Tunisia)
Vice-Chairpersons:	Mr Ricardo Cruz-Coke (Chile) Mr Koh Chong-Lek (Malaysia) Mr Lazare Poame (Côte d’Ivoire) Mr Joachim Schemel (Germany)
Rapporteur:	Mr Karel Komarek (Czech Republic).

7. In accordance with the Agenda, the Meeting initially established a Drafting Committee made up of representatives of the following 18 Member States: Belgium, Chile, Côte d’Ivoire, Germany, India, Indonesia, Italy, Japan, Lithuania, Luxembourg, Malaysia, Mexico, Poland, Portugal, Republic of Korea, the Netherlands, Tunisia and the United Kingdom. It was decided that the members of the Bureau would sit *ex officio* on the Drafting Committee, which would be open to any delegations wishing to participate in it.

8. In order to proceed with the revision of the text on the basis of the amendments proposed by participants during the time allotted, the Meeting later decided to establish an Editorial Board, including one representative of a Member State from each electoral group, as follows: Ms Ewa Bartnik (Poland), Mr Koh Chong-Lek (Malaysia), Mr Ricardo Cruz-Coke (Chile), Mr Lazare Poame (Côte d’Ivoire), Mr Joachim Schemel (Germany) and Mr Gamal I. Serour (Egypt). Mr Koh Chong-Lek was elected Chairperson of the Board, which was also assisted by the Chairperson of the IBC and the Rapporteur of the IBC Drafting Group.

9. The Chairperson of the Meeting indicated that, while the Meeting could continue until Sunday 29 June, the Meeting would carry on its work during evening sessions so as to complete its task if possible by 27 June.

II. PRESENTATION OF THE PRELIMINARY DRAFT OF THE INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA (26 MAY 2003)

10. Under Item 6 of the Agenda, the Chairperson invited the Chairperson of the IBC, Ms Michèle S. Jean, and the Rapporteur of the IBC Drafting Group, Mr Georges Kutukdjian, to present the Preliminary Draft of the International Declaration on Human Genetic Data (26 May 2003).

11. Ms Jean described the development of the preliminary draft in great detail, underscoring that despite its urgency and short period of time for elaboration, the project has been subject to much reflection and consultation. The IBC first considered the subject of human genetic data in 1999 and

has drafted two reports on the subject: “Confidentiality and Genetic Data” (BIO-503/99/CIB-6/GT-2/3) and “Human Genetic Data: Preliminary Study by the IBC on its Collection, Processing, Storage and Use” (SHS-503/01/CIB-8/3). Ms Jean reminded participants that UNESCO’s Director-General first requested the IBC to examine the possibility of drafting an international instrument on human genetic data in early 2001 and that the General Conference endorsed that initiative in November 2001 (31 C/Resolution 22). She also recalled that at its 165th session the Executive Board of UNESCO stated that UNESCO “should prepare, as a matter of urgency, an international declaration on human genetic data with due regard for human dignity and human rights and freedoms” (165 EX/Decision 3.4.2).

12. Ms Jean explained that the IBC Drafting Group met six times between February 2002 and May 2003 and that the IBC examined the resulting drafts at its ninth and tenth sessions (Montreal, November 2002 and Paris, May 2003) respectively. She explained that from January to March 2003, the IBC undertook an international written consultation and a public hearings day (Monaco, 28 February 2003). These consultations provided opportunities for different actors (including Member States, intergovernmental and non-governmental organizations, national bodies, specialists, former IBC members and stakeholders such as aboriginal groups, handicapped people, the medical community and private companies) to provide comments and suggestions on the outline, which were reflected in the preliminary draft.

13. Mr Kutukdjian reiterated the depth of reflection involved in the elaboration of the preliminary draft and drew attention to related reports of the IBC. He recalled that the declaratory form of the instrument was chosen for its appropriateness in the elaboration of principles that States can interpret taking into account their legal systems and different cultural, economic and social circumstances. The text addresses the purposes for which human genetic data may be collected, the stages involved and the principles that must be associated with these steps, including those involving non-discrimination, non-stigmatization, provision of and withdrawal of consent, the right to decide whether to be informed of the results of genetic tests, access, confidentiality, trade, benefit-sharing, destruction of genetic data and change of purpose. The preliminary draft aims to ensure respect for human dignity, to protect human rights and freedoms, to guide States in formulating legislation on human genetic data and to establish principles for best practices by the institutions and individuals involved.

14. Mr Kutukdjian then presented the principal changes that have been made to the outline based on input provided during consultations and the ninth and tenth sessions of the IBC, and which are reflected in the preliminary draft. In particular, the Drafting Group refined its explanation of why human genetic data have a special status, modified articles concerning consent (including its withdrawal, its applicability to minors, its written form and change of purpose), removed the requirement of a judicial decision for collection with regard to civil and criminal proceedings, expanded the limitations to confidentiality and consent so that they will not be required when national legislation so permits in accordance with international human rights law, adapted the text’s provisions for the destruction of genetic data to include cases in which public health, order and national security are concerned and modified the form of the articles addressing capacity-building, solidarity, education, training and the responsibilities of UNESCO.

III. EXAMINATION OF THE PRELIMINARY DRAFT OF THE INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA (26 MAY 2003)

15. Under Item 8 of the Agenda, representatives of States presented observations and comments of their governments with regard to the text of the Preliminary Draft of the International Declaration

on Human Genetic Data (26 May 2003). All participants from Member States, as well as observers, were invited to submit their written proposed amendments for consideration.

16. A total of 34 delegations of UNESCO's Member States, two observers from non-Member States, one representative of a United Nations organization and one observer from another intergovernmental organization participated in the general debate. Most speakers congratulated UNESCO, and in particular the IBC, for its work in elaborating the preliminary draft. Many applauded the quality of the text, recognizing it as an important extension to the Universal Declaration on the Human Genome and Human Rights (1997).

General considerations

17. Many speakers emphasized the need to ensure that the draft declaration be internally consistent, both in principles and terminology, and also consistent with other international human rights instruments, in particular the Universal Declaration on the Human Genome and Human Rights. The terminology used in the preliminary draft should also reflect the accepted language and definitions of the international community in general.

18. Many participants expressed a desire that the preliminary draft's language be more uniformly declaratory in nature and pointed out that some articles were more prescriptive than others. The participants agreed that insofar as possible the word "shall" would be replaced by "should" or by "may" in the text of the preliminary draft. When used in relation to the roles of the IBC and the IGBC in the implementation of the declaration, the word "shall" will be retained in the text. Following the example of the Universal Declaration on the Human Genome and Human Rights, the Meeting chose to use the term "international law of human rights" rather than "international human rights law" where applicable in the text.

19. Some delegates indicated that some provisions of the preliminary draft may be inconsistent with their national legislation, especially with regard to the role of national ethics committees, the destruction of human genetic data, benefit-sharing and collection of human genetic data for judicial purposes. Some considered that the use of a specific reference to national legislation where appropriate could respond to these concerns.

20. Participants brought up the question of whether the text should further attempt to balance protection of individuals, the public interest and freedom of thought, expression and inquiry. Some participants felt that the emphasis on benefit-sharing, consent and access to data could inhibit researchers, while others asserted that the preliminary draft implies no such restrictions. Many participants agreed that the preliminary draft should further emphasize the role of public interest and national security with regard to the collection, use and storage of genetic data, but it was stressed that, in line with other international instruments, the interests of individuals should predominate.

Definitions

21. Most participants applauded the use of definitions in the preliminary draft. The Meeting considered whether the list of definitions under the heading "Use of Terms" provided in the preliminary draft should be placed in the Explanatory Memorandum (SHS/EST/CONF.203/4), as a chapter in the preliminary draft or at the end of the text as a glossary. Cautioned that if these definitions were to have the moral force of an international instrument, they must be included in the text of the Declaration, and affirming their importance, the participants agreed that the definitions should appear as an article. It was decided that the article entitled "Aims and scope" should appear as Article 1 as this would immediately focus the purpose and principles of the declaration and

provide a concise introduction to the text, and that “Use of Terms” would appear as Article 2. Moreover, for ease of reference all definitions will be included in the same list, rather than sometimes instead appearing in footnotes.

22. Specific comments were made regarding the definition of data unlinked to identifiable persons. Several delegates asked that this definition be clarified, to clearly distinguish data that are irretrievably unlinked through the destruction of all information about the person who provided the sample from data that are unlinked through for example the replacement with a code of all information about that person.

Special status of genetic data

23. Some speakers raised the concern that not all human genetic data can be recognized as having a special status, in particular with regard to the legal and political spheres. They pointed out that not all types of human genetic data should be treated as equally “sensitive” and that for example the requirement for genetic counselling may not be applicable to all forms of collection of genetic data (such as, arguably, blood type).

Purposes

24. During the sensitive discussion of the acceptable purposes of collecting genetic data, concerns were expressed concerning the possible incompatibilities of the preliminary draft’s list of purposes with specific national legislation, in particular with regard to collection for forensic medicine, paternity tests and genetic tests for athletes. Some delegates argued that the formulation of the article would be appropriate provided a caveat be added that the purposes will be in accordance with national legislation.

25. For some, the preliminary draft should not address the collection of human genetic data for the purposes of forensic medicine in the same way as collection for the purposes of civil and criminal proceedings because in their countries these practices are dealt with under different laws and regulations. For others, the collection of human genetic data for forensic purposes could be addressed in the sections pertaining to collection for medical and scientific research purposes. Several speakers pointed out that in their countries, paternity cases are addressed in family law proceedings rather than civil and criminal proceedings and that the list of acceptable purposes for collection of genetic data should reflect such types of proceedings. Some participants cautioned that although the list of purposes may be extended, each purpose must be clearly defined, as too broad a list could open the door to abuse.

Consent and genetic counselling

26. Participants discussed at length the free and informed consent of individuals. Attention was drawn to the importance of provisions related to consent and to the fact that these provisions should refer not only to the collection of human genetic data, but also to their processing, use and storage.

27. The discussion included the need to further define the conditions of “free” consent and to provide for the informed consent of illiterate individuals and for the collection of genetic data from foetuses and cadavers. Many participants also referred to problems with conducting research among groups or populations, in particular in developing countries, where the difficulty of obtaining “informed” consent as defined in the declaration could prevent some groups from taking part in population genetics studies. While some participants said that requiring “free, informed and express” consent could prevent such people from exercising their right to participate in such research, others insisted that such provisions are crucial to protecting indigenous people’s rights.

28. All agreed that the future declaration should make specific reference to children. Although some participants suggested that a method should be outlined to allow parents, guardians or other authorities to consent to collection of genetic data from children, others warned about possible conflicts of interest between children and their parents or guardians. In this regard, some participants suggested that genetic screening and testing of children will normally only be performed when it has important implications for the health of the child and has regard to the best interest of the child.

29. With regard to the withdrawal of consent, it was recognized that the relevant article should better specify the cases in which withdrawal can feasibly be allowed. Some speakers mentioned cases in which, even in accordance with national laws, consent cannot be withdrawn, for example when human genetic data are collected for judicial purposes or in the framework of a diagnostic procedure. It was also argued that if written consent is required then the withdrawal of consent itself must be presented in writing, raising concerns of prejudice against illiterate persons.

30. Several different opinions were expressed concerning genetic counselling. Most speakers recognized the importance of offering genetic counselling when human genetic data are collected and some insisted that it should be mandatory. However, others pointed out that making genetic counselling mandatory may not be necessary for some procedures (such as possibly blood testing).

International cooperation and sharing of benefits

31. In general, participants supported the preliminary draft's provisions for international cooperation and benefit-sharing, in particular with donor communities from developing countries and scientific researchers from these countries. Several participants said these provisions should be strengthened. However, others stressed the importance that such provisions should not be in conflict with the patenting system and should be consistent with national standards regulating conduct of research and biological samples donation procedures. Still others warned that requiring benefits to be shared with persons and groups having taken part in the research could limit the ability of researchers to undertake many population-based genetic studies, in particular when rural or indigenous people are involved.

Monitoring and management framework

32. Even though a few delegates expressed their preference that the provision concerning the monitoring and management system be removed, several speakers underlined the importance of such a system in particular at the transnational level. The need for registration of genetics labs and the difficulty in monitoring private genetic data banks were discussed as was the issue of the confidentiality in particular with regard to population-based genetic studies.

IV. WORK OF THE EDITORIAL BOARD

33. The Editorial Board endeavoured to reconcile the various opinions expressed during the general debate, to consider all the written amendments and to finalize the text within the allotted time. The approach adopted by the Editorial Board consisted first of all in pinpointing central issues for discussion and in considering each written and oral amendment submitted by States.

34. The Secretariat had received written amendments from 23 States (Algeria, Belgium, Canada, Chile, Côte d'Ivoire, Czech Republic, Egypt, Finland, France, Germany, Greece, Iceland, India, Japan, Luxembourg, Mexico, Peru, Portugal, Republic of Korea, Switzerland, the Netherlands, Turkey and the United Kingdom), as well as from two Non-Member States (the Holy See and the

United States of America) and two intergovernmental organizations (the World Health Organization and the Council of Europe).

35. The Editorial Board produced a Draft Declaration in which all the proposed changes were visible. The Board decided not to pronounce on the issue of forensic medicine and civil and criminal proceedings. Not having taken a unique position concerning whether the article on sharing of benefits should enumerate possible forms of benefit-sharing or instead refer to benefit-sharing in a more general way, the Board opted to propose to the plenary meeting two possible formulations of the article for the final discussion and approval.

V. FURTHER CONSIDERATION OF THE PRELIMINARY DRAFT OF THE INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA (27 JUNE 2003)

36. At its final plenary meeting on 27 June 2003, the Meeting had before it the Draft Declaration resulting from the work of its Editorial Board. The Chairperson of the Editorial Board invited the participants to examine the Draft Declaration section by section and to decide in particular on those issues on which the Editorial Board did not arrive at a single position.

37. Participants generally agreed with amendments made to the text by the Editorial Board, but they wished to make some additional changes in order to better address some concerns expressed during the general debate, concerning *inter alia* the applicability of the declaration to proteomic data, the formulation of some definitions, the special status of human genetic data, purposes, in particular in the case of civil and criminal proceedings, consent, in particular from children and incapacitated adults, genetic counselling, change of purpose and destruction.

38. In some cases, such as procedures (Article 6) and genetic counselling (Article 11), participants agreed not to use of the words “shall” or “should” but rather to use the phrase “it is ethically imperative”.

39. With regard to sharing of benefits, participants opted to retain the original formulation of the article but chose to reflect explicitly the need to develop and strengthen the capacity of developing countries to collect and process human genetic data.

40. Finally, the Meeting agreed unanimously to amend the preamble in order to include a specific reference to the relevant United Nations Economic and Social Council resolutions and to explain from the beginning of the text the reasons that human genetic data have a special status.

41. The Meeting entrusted the Secretariat both with ensuring that the text of the draft is not repetitive and conforms with the international law of human rights and with other international instruments in the United Nations system and also with making specific linguistic rather than substantive revisions to the text.

VI. ADOPTION OF THE DRAFT INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA AND CONSIDERATION OF THE DRAFT FINAL REPORT

42. At its final plenary session on 27 June 2003, the Meeting adopted the Draft International Declaration on Human Genetic Data by consensus.

43. While granting that there was still room for improvement in the Draft Declaration, speakers agreed that it was the result of both the spirit of cooperation that had been present throughout the

Meeting and of the endeavour to strike a balance in order to meet the aspirations and needs of the States.

44. However, in acknowledgement of the reservations expressed by some participants, the Meeting did not wish to pronounce definitively on the extent to which the future declaration should apply to forensic medicine and civil and criminal proceedings. The related provisions in the Draft Declaration (seventh preambular paragraph, Articles 5, 17 and 21) therefore appear in brackets.

45. The Rapporteur, Mr Karel Komarek (Czech Republic), then presented the main lines of his report, highlighting the primary sections of the report and indicating that he would limit himself to a broad outline of the views expressed in the plenary meetings and in the Editorial Board. He further indicated that he would finalize his report in light of the latest debates.

VII. CLOSURE

46. The Assistant Director-General for Social and Human Sciences, Mr Pierre Sané, pointed out that the Meeting had succeeded in reaching a consensus on the Draft Declaration and only few issues, reflected in the bracketed text, required further discussion. To this end, there were three possible paths of action:

- a second meeting of government experts could be convened in September 2003 in order to specifically address the provisions remaining in brackets;
- the Executive Board, at its 166th session in September 2003, could examine the Draft Declaration and transmit it to the General Conference accompanied by specific recommendations on the bracketed provisions;
- Member States could allot time to address the bracketed provisions during the debate on this item at the 32nd session of the General Conference.

The Secretariat will consult with the Director-General, before formally committing to one of these options.

47. The Chairperson, reflecting comments of many participants, said that the work accomplished jointly by the Meeting had produced a result that, although awaiting final improvements, nevertheless constituted an extremely solid foundation. He underscored the spirit of tolerance that had pervaded the work and the relevance of the statements and had made it possible to further enrich thinking on the subject. The participants, the Chairperson of the IBC, the Rapporteur of the IBC Drafting Group and the Secretariat were thanked and the Chairperson declared the Meeting closed.

ANNEX B

**STATES AND ORGANIZATIONS REPRESENTED AT
THE MEETING OF GOVERNMENT EXPERTS RESPONSIBLE FOR FINALIZING
THE DRAFT INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA**

I. Member States

Algeria	Madagascar
Argentina	Malaysia
Austria	Mexico
Azerbaijan	Morocco
Belgium	Netherlands
Brazil	Pakistan
Canada	Peru
Chile	Philippines
Colombia	Poland
Costa Rica	Portugal
Côte d'Ivoire	Saudi Arabia
Czech Republic	Senegal
Egypt	Serbia and Montenegro
El Salvador	Spain
Finland	Sudan
France	Swaziland
Germany	Switzerland
Greece	Togo
Iceland	Tunisia
India	Turkey
Indonesia	Ukraine
Italy	United Arab Emirates
Japan	United Kingdom
Korea, Republic of	Uruguay
Kuwait	United Republic of Tanzania
Latvia	Uzbekistan
Libyan Arab Jamahiriya	Venezuela
Lithuania	Yemen
Luxembourg	

II. RESOURCE PERSONS

The Chairperson of the International Bioethics Committee of UNESCO (IBC)

The Co-Chairperson of the Drafting Group of the IBC

The Rapporteur of the Drafting Group of the IBC

III. OBSERVERS

A. Permanent Observation Missions

Holy See

Palestine

United States of America

B. United Nations Organizations

World Health Organization (WHO)

C. Intergovernmental organizations

Council of Europe

Arab League Educational, Cultural and Scientific Organization (ALECSO)

Islamic Educational, Scientific and Cultural Organization (ISESCO)

Organization for Economic Cooperation and Development (OECD)

D. Non-governmental organizations

European Academy of Arts, Sciences and Humanities

World Academy of Biomedical Technologies (WABT)

World Federation of Scientific Workers (WFSW)



32 C/29 Add. Rev.
3 October 2003
Original: English & French only

Item 8.7 of the agenda

DRAFT INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

ADDENDUM

OUTLINE

Source: 167 EX/Decision 5.3.

Background: At its 167th session, the Executive Board examined document 167 EX/18 and, by its decision 5.3, recommended to the General Conference that it adopt a resolution included in that document.

Purpose: This document gives an account of the debate held at the 167th session of the Executive Board on agenda item 5.3 (Report by the Director-General on the finalization of the draft international declaration on human genetic data) and includes the resolution which the Executive Board recommends that the General Conference adopt.

Decision required: paragraph 13.

I. INTRODUCTION

1. The Director-General wished to include item 5.3 “Report by the Director-General on the finalization of the draft international declaration on human genetic data” in the agenda of the 167th session of the Executive Board in order to inform the Board of the latest progress made in the work done by the Organization since the 166th session to finalize the draft declaration and in order that the Board might, if appropriate, make recommendations in that regard to the General Conference.

2. By 167 EX/Decision 5.3, the Executive Board invited the Director-General to “inform the General Conference of the observations made at its 167th session concerning the draft international declaration on human genetic data”. This document gives an account of the debate held on that item at the 167th session of the Executive Board together with its recommendations, and contains the resolution which the Executive Board recommends that the General Conference adopt.

II. DEBATE AT THE 167TH SESSION OF THE EXECUTIVE BOARD ON THE DRAFT INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

3. The representative of the Director-General, ADG/SHS, introduced the agenda item, describing the different stages in the preparation of the draft declaration which, at the end of the process, was finalized at the meeting of government experts convened by the Director-General in Paris, from 25 to 27 June 2003.

4. Twenty-one representatives of Member States took the floor during the debate on this item and the discussion of the corresponding decision. The speakers congratulated UNESCO, and in particular the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC), on the work done, emphasizing the quality of the text and the balance achieved in the draft declaration.

5. Some delegates acknowledged how difficult it had been to finalize the text of the declaration – as a result partly of the limited room for manoeuvre allowed by the abundance of domestic legislation that already existed on the matter or indirectly applied to genetic data – in particular in the field of forensic medicine and civil and criminal proceedings (for which reason the relevant provisions were shown in square brackets). Other delegates suggested that the square brackets should be removed. All delegates reaffirmed the desirability of adopting such a declaration at the next session of the General Conference in order to meet the fundamental concerns of the international community raised by the rapid progress of research in genetics and its applications.

6. The delegates stressed that the text of the declaration must be in keeping with the provisions and terminology both of the Universal Declaration on the Human Genome and Human Rights of 1997 and of the Universal Declaration of Human Rights of 1948. Moreover, the future declaration should take into account the existence of all international instruments and agreements, notably in regard to international cooperation and the economic implications of the use of genetic data – in particular the patenting system.

7. Some delegates stressed the fact that the new declaration would serve as a framework and an incentive for those States that had not yet established a legislative framework on the subject. Others pointed out that since scientific developments were not as rapid or as advanced in certain countries, such States should be provided with the appropriate means to enable them to implement the future declaration effectively.

8. Some specific aspects of the draft declaration were highlighted, such as the problems relating to confidentiality, the need to encourage the publication and broad dissemination of the findings of research in genetics, and the possible use of genetic data for discriminatory purposes.

9. In conclusion, while some delegates proposed amendments to the draft declaration, it was suggested that the Board recommend the establishment during the 32nd session of the General Conference of a working group of Commission III to prepare the debate on that item in commission and to facilitate deliberations with a view to the adoption of the draft international declaration on human genetic data.

10. In his reply, the representative of the Director-General recalled that the draft declaration was, in its final form, a text prepared by government experts, which was transmitted to the General Conference (see document 32 C/29) accompanied by the recommendations and observations formulated by the Executive Board at its 167th session.

11. It was also decided that any written amendments received by the Secretariat before 26 September would be made available to the working group which was to be established within Commission III.

III. CONCLUSION AND RESOLUTION RECOMMENDED BY THE EXECUTIVE BOARD FOR ADOPTION BY THE GENERAL CONFERENCE

12. At the close of its debate, the Executive Board, by 167 EX/Decision 5.3, recommended to the General Conference that it “establish a working group of Commission III to prepare the relevant deliberations with a view to facilitating the adoption of the draft international declaration on human genetic data contained in document 32 C/29, at its 32nd session, taking into account the proposals and observations by Member States”.

13. By the same decision, the Executive Board further recommended to the General Conference that, at its 32nd session, it adopt the following resolution:

The General Conference,

Considering the International Declaration on Human Genetic Data adopted on ... October 2003,

1. Calls upon Member States:

- (a) to make every effort to adopt measures, whether of a legislative, administrative or other character, to give effect to the principles set out in the Declaration, in accordance with the international law of human rights; such measures should be supported by action in the sphere of education, training and public information;
- (b) to notify the Director-General regularly of any pertinent information on steps taken by them to implement the principles set forth in the Declaration, pursuant to Article 25 thereof;
- (c) to promote ethics education and training at appropriate levels, and to encourage programmes for information and the circulation of knowledge concerning human genetic data;

2. Invites the Director-General:

- (a) to take appropriate steps to ensure the follow-up to the Declaration, including its dissemination and translation into a large number of languages;
- (b) to take the necessary steps to enable the International Bioethics Committee of UNESCO (IBC) and the Intergovernmental Bioethics Committee (IGBC) to contribute appropriately to the implementation of the Declaration and dissemination of the principles set forth therein;
- (c) to report to the General Conference at its 33rd session on the implementation of this resolution.



32 C/29 Add.2
8 October 2003
Original: French/English

Item 8.7 of the agenda

DRAFT INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

ADDENDUM 2

OUTLINE

Source: 167 EX/Decision 5.3.

Background: In accordance with 167 EX/Decision 5.3, Commission III of the 32nd session of the General Conference established a working group to prepare the deliberations relating to the draft international declaration on human genetic data, with a view to facilitating its adoption.

Purpose: The text of the draft declaration, as finalized by the working group of Commission III on 7 October 2003, is reproduced in Section II of this document.

I. INTRODUCTION

1. In accordance with 167 EX/Decision 5.3, Commission III of the 32nd session of the General Conference established a working group to prepare the deliberations relating to the draft international declaration on human genetic data, with a view to facilitating its adoption by the General Conference at its 32nd session.
2. The working group, chaired by Mr Bart Wijnberg (Netherlands) and comprising 20 representatives of Member States and two observers, met on 6 and 7 October 2003.
3. The text of the draft declaration as finalized by the working group, reproduced in Section II, replaces the text reproduced in section III of document 32 C/29.

II. DRAFT INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

The General Conference,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the two International United Nations Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the International United Nations Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Economic and Social Council Resolutions 2001/39 on Genetic Privacy and Non-Discrimination of 26 July 2001 and 2003/232 on Genetic Privacy and Non-Discrimination of 22 July 2003, the ILO Convention (No. 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPs Agreement and Public Health of 14 November 2001, the other international human rights instruments adopted by the United Nations and the specialized agencies of the United Nations system,

Recalling more particularly the Universal Declaration on the Human Genome and Human Rights which it adopted, unanimously and by acclamation, on 11 November 1997 and which was endorsed by the United Nations General Assembly on 9 December 1998, and the Guidelines for the implementation of the Universal Declaration on the Human Genome and Human Rights which it endorsed on 16 November 1999 by 30 C/Resolution 23,

Welcoming the broad public interest worldwide in the Universal Declaration on the Human Genome and Human Rights, the firm support it has received from the international community and its impact in Member States drawing upon it for their legislation, regulations, norms and standards, and ethical codes of conduct and guidelines,

Bearing in mind the international and regional instruments, national laws, regulations and ethical texts relating to the protection of human rights and fundamental freedoms and to respect for human dignity as regards the collection, processing, use and storage of scientific data, as well as of medical data and personal data,

Recognizing that genetic information is part of the overall spectrum of medical data and that the information content of any medical data, including genetic data and proteomic data, is highly contextual and dependent on the particular circumstances,

Also recognizing that human genetic data have a special status on account of their sensitive nature since they can be predictive of genetic predispositions concerning individuals and that the power of predictability can be stronger than assessed at the time of deriving the data; they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group; they may contain information the significance of which is not necessarily known at the time of the collection of biological samples; and they may have cultural significance for persons or groups,

Emphasizing that all medical data, including genetic data and proteomic data, regardless of their apparent information content, should be treated with the same high standards of confidentiality,

Noting the increasing importance of human genetic data for economic and commercial purposes,

Having regard to the special needs and vulnerabilities of developing countries and the need to reinforce international cooperation in the field of human genetics,

Considering that the collection, processing, use and storage of human genetic data are of paramount importance for the progress of life sciences and medicine, for their applications, and for the use of such data for non-medical purposes,

Also considering that the growing amount of personal data collected makes genuine irretrievability increasingly difficult,

Aware that the collection, processing, use and storage of human genetic data have potential risks for the exercise and observance of human rights and fundamental freedoms, and respect for human dignity,

Noting that the interests and welfare of the individual should have priority over the rights and interests of society and research,

Reaffirming the principles established in the Universal Declaration on the Human Genome and Human Rights and the principles of equality, justice, solidarity and responsibility as well as respect for human dignity, human rights and fundamental freedoms, particularly freedom of thought and expression, including freedom of research and privacy and security of person, which must underlie the collection, processing, use and storage of human genetic data,

Proclaims the principles that follow and adopts the present Declaration.

A. GENERAL PROVISIONS

Article 1: Aims and scope

(a) The aims of this Declaration are: to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples from which they are derived, referred to hereinafter as “biological samples”, in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research; to set out the principles which should guide States in the formulation of their

legislation and their policies on these issues; and to form the basis for guidelines of good practices in these areas for concerned institutions and individuals.

(b) Any collection, processing, use and storage of human genetic data, human proteomic data and biological samples, shall be consistent with the international law of human rights.

(c) The provisions of this Declaration apply to the collection, processing, use and storage of human genetic data, human proteomic data and biological samples, except in the investigation, detection and prosecution of criminal offences and in parentage testing that are subject to domestic law that is consistent with the international law of human rights.

Article 2: Use of terms

For the purposes of this Declaration, the terms used have the following meanings:

- (i) *Human genetic data*: Information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis;
- (ii) *Human proteomic data*: Information pertaining to an individual's proteins including their expression, modification and interaction;
- (iii) *Consent*: Any freely given specific, informed and express agreement of an individual to his or her genetic data being collected, processed, used and stored;
- (iv) *Biological samples*: Any sample of biological material (for example blood, skin and bone cells or blood plasma) in which nucleic acids are present and which contains the characteristic genetic make-up of an individual;
- (v) *Population-based genetic study*: A study which aims at understanding the nature and extent of genetic variation among a population or individuals within a group or between individuals across different groups;
- (vi) *Behavioural genetic study*: A study that aims at establishing possible connections between genetic characteristics and behaviour;
- (vii) *Invasive procedure*: Biological sampling using a method involving intrusion into the human body, such as obtaining a blood sample by using a needle and syringe;
- (viii) *Non-invasive procedure*: Biological sampling using a method which does not involve intrusion into the human body, such as oral smears;
- (ix) *Data linked to an identifiable person*: Data that contain information, such as name, birth date and address, by which the person from whom the data were derived can be identified;
- (x) *Data unlinked to an identifiable person*: Data that are not linked to an identifiable person, through the replacement of, or separation from, all identifying information about that person by use of a code;
- (xi) *Data irretrievably unlinked to an identifiable person*: Data that cannot be linked to an identifiable person, through destruction of the link to any identifying information about the person who provided the sample;

- (xii) *Genetic testing*: A procedure to detect the presence or absence of, or change in, a particular gene or chromosome, including an indirect test for a gene product or other specific metabolite that is primarily indicative of a specific genetic change;
- (xiii) *Genetic screening*: Large-scale systematic genetic testing offered in a programme to a population or subsection thereof intended to detect genetic characteristics in asymptomatic people;
- (xiv) *Genetic counselling*: A procedure to explain the possible implications of the findings of genetic testing or screening, its advantages and risks and where applicable to assist the individual in the long-term handling of the consequences. It takes place before and after genetic testing and screening;
- (xv) *Cross-matching*: Matching of information about an individual or a group contained in various data files set up for different purposes.

Article 3: Person's identity

Each individual has a characteristic genetic make-up. Nevertheless, a person's identity should not be reduced to genetic characteristics, since it involves complex educational, environmental and personal factors and emotional, social, spiritual and cultural bonds with others and implies a dimension of freedom.

Article 4: Special status

- (a) Human genetic data have a special status because:
 - (i) they can be predictive of genetic predispositions concerning individuals;
 - (ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs;
 - (iii) they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples;
 - (iv) they may have cultural significance for persons or groups.
- (b) Due consideration should be given to the sensitivity of human genetic data and an appropriate level of protection for these data and biological samples should be established.

Article 5: Purposes

Human genetic data and human proteomic data may be collected, processed, used and stored only for the purposes of:

- (i) diagnosis and health care, including screening and predictive testing;
- (ii) medical and other scientific research, including epidemiological, especially population-based genetic studies, as well as anthropological or archaeological studies, collectively referred to hereinafter as "medical and scientific research";

- (iii) forensic medicine and civil, criminal and other legal proceedings, taking into account the provisions of Article 1(c);
- (iv) or any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights, and the international law of human rights.

Article 6: Procedures

(a) It is ethically imperative that human genetic data and human proteomic data be collected, processed, used and stored on the basis of transparent and ethically acceptable procedures. States should endeavour to involve society at large in the decision-making process concerning broad policies for the collection, processing, use and storage of human genetic data and human proteomic data and the evaluation of their management, in particular in the case of population-based genetic studies. This decision-making process, which may benefit from international experience, should ensure the free expression of various viewpoints.

(b) Independent, multidisciplinary and pluralist ethics committees should be promoted and established at national, regional, local or institutional levels, in accordance with the provisions of Article 16 of the Universal Declaration on the Human Genome and Human Rights. Where appropriate, ethics committees at national level should be consulted with regard to the establishment of standards, regulations and guidelines for the collection, processing, use and storage of human genetic data, human proteomic data and biological samples. They should also be consulted concerning matters where there is no domestic law. Ethics committees at institutional or local levels should be consulted with regard to their application to specific research projects.

(c) When the collection, processing, use and storage of human genetic data, human proteomic data or biological samples are carried out in two or more States, the ethics committees in the States concerned, where appropriate, should be consulted and the review of these questions at the appropriate level should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.

(d) It is ethically imperative that clear, balanced adequate and appropriate information shall be provided to the person whose prior, free, informed and express consent is sought. Such information shall, alongside with providing other necessary details, specify the purpose for which human genetic data and human proteomic data are being derived from biological samples, and are used and stored. This information should indicate, if necessary, risks and consequences. This information should also indicate that the person concerned can withdraw his or her consent, without coercion, and which should entail neither a disadvantage nor a penalty for the person concerned.

Article 7: Non-discrimination and non-stigmatization

(a) Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, or a group or communities.

(b) In this regard, appropriate attention should be paid to the findings of population-based genetic studies and behavioural genetic studies and their interpretations.

B. COLLECTION

Article 8: Consent

- (a) Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic data or biological samples, whether through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions. Limitations on this principle of consent should only be prescribed for compelling reasons by domestic law, consistent with the international law of human rights.
- (b) When, in accordance with domestic law, a person is incapable of giving informed consent, authorization should be obtained from the legal representative, in accordance with domestic law. The legal representative should have regard to the best interest of the person concerned.
- (c) An adult not able to consent should as far as possible take part in the authorization procedure. The opinion of a minor should be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity.
- (d) In diagnosis and health care, genetic screening and testing of minors and adults not able to consent will normally only be ethically acceptable when it has important implications for the health of the person and has regard to his or her best interest.

Article 9: Withdrawal of consent

- (a) When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. In accordance with the provisions of Article 6(d), withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned.
- (b) When a person withdraws consent, the person's genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned.
- (c) If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person's wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed.

Article 10: The right to decide whether or not to be informed about research results

When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in such a research. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results.

Article 11: Genetic counselling

It is ethically imperative that when genetic testing that may have significant implications for a person's health is being considered, genetic counselling should be made available in an appropriate

manner. Genetic counselling should be non-directive, culturally adapted and consistent with the best interest of the person concerned.

Article 12: Collection of biological samples for forensic medicine or in civil, criminal and other legal proceedings

When human genetic data or human proteomic data are collected for the purposes of forensic medicine or in civil, criminal and other legal proceedings, including parentage testing, the collection of biological samples, *in vivo* or post-mortem, should be made only in accordance with domestic law, consistent with the international law of human rights.

C. PROCESSING

Article 13: Access

No one should be denied access to his or her own genetic data or proteomic data unless such data are irretrievably unlinked from that person as the identifiable source or unless domestic law limits such access in the interest of public health, public order or national security.

Article 14: Privacy and Confidentiality

(a) States should endeavour to protect the privacy of individuals and the confidentiality of human genetic data linked to an identifiable person, a family or, where appropriate, a group, in accordance with domestic law consistent with the international law of human rights.

(b) Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law that is consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights. The privacy of an individual participating in a study using human genetic data, proteomic data or biological samples should be protected and the data should be treated as confidential.

(c) Human genetic data, human proteomic data and biological samples collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples.

(d) Human genetic data, human proteomic data and biological samples collected for medical and scientific research purposes, can remain linked to an identifiable person, only if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned is protected in accordance with domestic law.

(e) Human genetic data and human proteomic data should not be kept in a form which allows the data subject to be identified for any longer than is necessary for achieving the purposes for which they were collected or subsequently processed.

Article 15: Accuracy, reliability, quality and security

The persons and entities responsible for the processing of human genetic data, human proteomic data and biological samples should take the necessary measures to ensure the accuracy, reliability,

quality and security of the human genetic data and the processing of biological samples. They should exercise rigour, caution, honesty and integrity in the processing and interpretation of human genetic data, human proteomic data or biological samples, in view of their ethical, legal and social implications.

D. USE

Article 16: Change of purpose

(a) Human genetic data, human proteomic data and the biological samples collected for one of the purposes set out in Article 5 should not be used for a different purpose that is incompatible with the original consent, unless the prior, free, informed and express consent of the person concerned is obtained according to the provisions of Article 8(a) or unless the proposed use, decided by domestic law, corresponds to an important public interest reason and is consistent with the international law of human rights. If the person concerned lacks the capacity to consent, the provisions of Article 8(b) and (c) should apply *mutatis mutandis*.

(b) When the prior, free, informed and express consent cannot be obtained or in the case of data irretrievably unlinked to an identifiable person, human genetic data may be used in accordance with domestic law or in accordance with the provisions of Article 6(b).

Article 17: Stored biological samples

(a) Stored biological samples collected for purposes other than set out in Article 5 may be used to produce human genetic data or human proteomic data with the prior, free, informed and express consent of the person concerned. However, domestic law may provide that if such data have significance for medical and scientific research purposes e.g. epidemiological studies, or public health purposes, they may be used for those purposes, following the consultation procedures set out in Article 6(b).

(b) The provisions of Article 12 should apply *mutatis mutandis* to stored biological samples used to produce human genetic data for forensic medicine.

Article 18: Circulation and international cooperation

(a) States should regulate, in accordance with their domestic law and international agreements, the cross-border flow of human genetic data, human proteomic data and biological samples, so as to foster international medical and scientific cooperation and ensure fair access to this data. Such a system should seek to ensure that the receiving party provides adequate protection in accordance with the principles set out in this Declaration.

(b) States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning human genetic data and human proteomic data and, in that regard, to foster scientific and cultural cooperation, particularly between industrialized and developing countries.

(c) Researchers should endeavour to establish cooperative relationships, based on mutual respect with regard to scientific and ethical matters and, subject to the provisions of Article 14, should encourage the free circulation of human genetic data and human proteomic data, in order to foster the sharing of scientific knowledge, provided that the principles set out in this Declaration are observed by the parties concerned. Towards this goal, they should also endeavour to publish in due course the results of their research.

Article 19: Sharing of benefits

(a) In accordance with domestic law or policy and international agreements, benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community. In giving effect to these principles, benefits may take any of the following forms:

- (i) special assistance to the persons and groups that have taken part in the research;
- (ii) access to medical care;
- (iii) provision of new diagnostics, facilities for new treatments or drugs stemming from the research;
- (iv) support for health services;
- (v) capacity-building facilities for research purposes;
- (vi) development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems;
- (vii) any other form consistent with the principles set out in this Declaration.

(b) Limitations in this respect could be provided by domestic law and international agreements.

E. STORAGE**Article 20: Monitoring and management framework**

States may consider establishing a framework for the monitoring and management of human genetic data, human proteomic data and biological samples based on the principles of independence, multidisciplinary, pluralism and transparency as well as the principles set out in this Declaration. This framework could also deal with the nature and purposes of the storage of these data.

Article 21: Destruction

(a) The provisions of Article 9 apply *mutatis mutandis* in the case of stored human genetic data, human proteomic data and biological samples.

(b) Human genetic data, human proteomic data and the biological samples collected from a suspect in the course of a criminal investigation should be destroyed when they are no longer necessary, unless otherwise provided for by domestic law consistent with the international law of human rights.

(c) Human genetic data, human proteomic data and biological samples should be available for forensic purposes and civil proceedings only for as long as they are necessary for those proceedings, unless otherwise provided for by domestic law consistent with the international law of human rights.

Article 22: Cross-matching

Consent should be essential for cross-matching of human genetic data, human proteomic data or biological samples stored for diagnostic and health care purposes and for medical and other

scientific research purposes, unless otherwise provided for by domestic law for compelling reasons and consistent with the international law of human rights.

F. PROMOTION AND IMPLEMENTATION

Article 23: Implementation

(a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with the international law of human rights. Such measures should be supported by action in the sphere of education, training and public information.

(b) In the framework of international cooperation, States should endeavour to enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing of scientific knowledge concerning human genetic data and of the related know-how.

Article 24: Ethics education, training and information

In order to promote the principles set out in this Declaration, States should endeavour to foster all forms of ethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about human genetic data. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large. In this regard, States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 25: Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out therein. On a collaborative basis, the two Committees should be responsible for its monitoring and for the evaluation of its implementation, *inter alia*, on the basis of reports provided by States. The two Committees should be responsible in particular for the formulation of any opinion or proposal likely to further the effectiveness of this Declaration. They should make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference.

Article 26: Follow-up action by UNESCO

UNESCO shall take appropriate action to follow up this Declaration so as to foster progress of the life sciences and their applications through technologies, based on respect for human dignity and the exercise and observance of human rights and fundamental freedoms.

Article 27: Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity, including, in particular, the principles set out in this Declaration.