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UNESCO  
UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS  
HANDBOOK ON THE DECLARATION  
COMMENTARY ON ARTICLE 1 ("SCOPE")

Michael Kirby

*Article 1 - Scope*

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Drafting history

Article 1 underwent comprehensive change at several stages during the drafting process of the Declaration. The evolution of the text of this Article provides a critical insight into the overall development of the Declaration and the intended meaning of the Article in its final form.

There were six official drafts of the Declaration prepared by the IBC Drafting Group prior to the adoption of the final text by the Thirty-third Session of the General Conference of UNESCO in October 2005.<sup>1</sup> A brief chronology of these drafts as follows:<sup>2</sup>

30 April 2004	Draft outline of the structure of the Declaration finalised by the IBC Drafting Group
15 June 2004	First draft finalised by the IBC Drafting Group
27 July 2004	Second draft finalised by the IBC Drafting Group
27 August 2004	Third draft finalised by the IBC Drafting Group

<sup>1</sup> Resolution on the Universal Declaration on Bioethics and Human Rights (33 C/Resolution 36).

<sup>2</sup> All documents quoted in this section are sourced from: "Towards the Universal Declaration on Bioethics and Human Rights: The process of elaboration" (2006) *United Nations Education, Scientific and Cultural Organisation*.

15 December 2004	Fourth draft finalised by the IBC Drafting Group
9 February 2005	Preliminary Draft Declaration finalised

A note accompanying the text of the Preliminary Draft Declaration describes the process to that point in this way:

"This Preliminary Draft Declaration on Universal Norms on Bioethics was finalized by IBC at its extraordinary session on 28 January 2005 after six meetings of its Drafting Group held between April and December 2004, three sessions of IBC (April 2004, August 2004, January 2005), two written consultations (January-March 2004 and October-December 2004), numerous consultations at international, regional and national levels (including within the framework of the UN Inter-Agency Committee on Bioethics), a session of IGBC and a joint session of IBC and IGBC (January 2005)."

Following the finalisation of the Preliminary Draft Declaration, responsibility for the passage of the text was transferred from the IBC to the Intergovernmental Meeting of Experts. These experts represented UNESCO Member States and met officially in April and June of 2005. The first meeting established a Drafting Group and elected a Bureau responsible for steering negotiations and finalising the text prior to its official adoption by the General Conference of UNESCO.

Initial form of Article 1

At the first meeting of the IBC Drafting Group in April 2004, a draft outline of the structure of the Declaration was formed:<sup>3</sup>

**Aims and Scope**

- To ensure the application of science for the welfare of human beings and the development of humanity
- The declaration should underline the positive aspects of science and technology progress
- The scope should be oriented towards the human being

Following the release of this initial outline, the IBC Drafting Group agreed to separately define the Declaration's field of application (the "Scope"), as distinct from the goals targeted in the principles set forth in the Declaration (the "Aims").<sup>4</sup> This structure was maintained in all subsequent drafts and the final text.

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<sup>3</sup> Draft outline of the structure of the Declaration on Universal Norms on Bioethics, 30 June 2004.

<sup>4</sup> See: Report of the second meeting of the IBC Drafting Group for the elaboration of a declaration on universal norms on bioethics, 2-3 June 2004.

Evolution of the text of Article 1

The first official draft prepared by the IBC Drafting Group, dated 15 June 2004, defined the Scope of the Declaration as follows:<sup>5</sup>

***Scope***

***Bioethics, Humanity [Humankind / Human Beings] and the Biosphere***

This Declaration states the principles of bioethics primarily affecting [related to] human beings, while recognizing that human beings, as an integral part of the biosphere, have responsibilities and duties towards all other forms of life.

***Human dignity, human rights and fundamental freedoms***

The principles set out in this Declaration are founded on [are drawn from/ flow from] the respect for human dignity and the protection of human rights and fundamental freedoms [, in accordance with international human rights law].

***Consensus, diversity and pluralism***

- a) This Declaration affirms [states] that, through the universal principles set out therein based on shared values, common

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<sup>5</sup> See: Elaboration of the Declaration on Universal Norms and Bioethics: First outline of a text, 15 June 2004.

positions [decisions / solutions] in the field of bioethics should be reached for the benefit of humanity as a whole.

- b) This Declaration acknowledges that ethical issues raised by scientific and technological development are set [reflected] in the cultural, philosophical and religious bedrock of the various human communities and that in some cases they should be addressed in the spirit of cultural pluralism inherent in bioethics.

It was evident from the outset that Article 1 would reinforce "the human being" as the primary field of the Declaration's application. Although this focus would remain in the final text, it was not until the later stages of the drafting process that the Scope was refined to be two-fold. That is, the Declaration was expressed as being "addressed" to "States", but "applicable" to "human beings".

The text of Article 1 was substantially revised in the second draft, dated 27 July 2004.<sup>6</sup> This draft reflected the desire of the IBC Drafting Group's to condense the text and remove unnecessary repetition with

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<sup>6</sup> Elaboration of the Declaration on Universal Norms and Bioethics: First outline of a text, 27 July 2004.

other provisions relating to "General Principles".<sup>7</sup> Thus, the second draft read.<sup>8</sup>

### *Scope*

The principles set out in this Declaration:

- (i) apply to human beings, while recognizing that human beings have responsibilities and duties towards other forms of life in the biosphere, and
  
- (ii) apply to issues raised by scientific and technological developments and their applications, as well as their availability and access.

This text remained unchanged in the third draft, dated 27 August 2004. Between October and December 2004, the IBC Drafting Group engaged in a period of extensive consultation, both written and oral, with key stakeholders, including Member States of UNESCO, NGOs and intergovernmental experts.<sup>9</sup> The revised text emerging from these consultations was a direct product of the feedback received. The

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<sup>7</sup> Report of the third meeting of the IBC Drafting Group for the elaboration of a declaration on universal norms on bioethics, 8-9 July 2004.

<sup>8</sup> Elaboration of the Declaration on Universal Norms and Bioethics: Second outline of a text, 27 July 2004.

<sup>9</sup> Reports of the written consultation on the third outline of a declaration on universal norms on bioethics, October-December 2004.

suggestions made, for example, by the United States, Monaco, Canada and the Israel National Bioethics Committee, found expression in the text. Following these consultations, a revised draft was released, dated 15 December 2004:<sup>10</sup>

### *Scope*

- a) The principles set out in this Declaration:
  - (i) apply, as appropriate, to individuals, families, groups, communities as well as to public and private institutions, corporations and States and humankind as a whole;
  - (ii) apply to bioethical issues;
  - (iii) apply to any related decision or practice.
  
- b) The principles set out in this Declaration apply to human beings, while recognizing that they have responsibilities towards other forms of life in the biosphere.

Despite this progress, the text again changed considerably prior to the release of the Preliminary Draft Declaration on 9 February 2005.<sup>11</sup> These changes reflected the intensity of debate amongst the IBC Drafting

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<sup>10</sup> Elaboration of the Declaration on Universal Norms and Bioethics: Fourth outline of a text, 15 December 2004.

<sup>11</sup> Preliminary Draft Declaration on Bioethics, 9 February 2005.



Group and the IBC generally on the precise application of the Declaration. The amendments followed a joint session of the IBC and the Intergovernmental Bioethics Committee (IGBC), as well as an extraordinary session of the IBC, both held in late January 2005. For the first time, the provision included an express demarcation between "decision-makers" in the fields of bioethics, and those to whom the decisions applied:

### *Scope*

The principles set out in this Declaration apply as appropriate and relevant:

- (i) to decisions or practices made or carried out in the application of medicine, life and social sciences to individuals, families, groups and communities; and
- (ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States.

However, clearly, given the regularity of changes to the text, debate over the wording of Article 1 was far from complete. The Report of the First Intergovernmental Meeting of Experts aimed at finalising the text of the Declaration, dated 6 April 2005, stated that the text would require further revision "taking account of the debates being held on the field of

application of the Declaration".<sup>12</sup> Indeed, the genesis of the final form of Article 1 appears evident from the following passage contained within that report:

"Some delegates also insisted that [Article 1] clearly state to whom the Declaration is addressed, making a distinction between the States and the other actors concerned, in accordance with the discussions held on the recipients of the text."<sup>13</sup>

It was in response to this debate that the Chairperson of the Intergovernmental Meeting of Experts, Mr Pablo Sader (Uruguay), prepared a document to be considered by delegates in the lead-up to the Second Intergovernmental Meeting of Experts in June 2005. His summation of the key points of division, together with suggestions as to how these could be resolved, was particularly insightful:<sup>14</sup>

#### **1. Use of terms and Scope (articles 1 and 2)**

The fundamental underlying conceptual divergence seems to be the extent of the notion of bioethics as applied to this declaration. There are two schools of thought: a broader one that locates bioethics in its social and environmental context and another one

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<sup>12</sup> See Report of the first intergovernmental meeting of experts aimed at finalizing a draft declaration on universal norms on bioethics, 4-6 April 2005.

<sup>13</sup> Ibid.

<sup>14</sup> Non-paper (thoughts and questions raised by the Chairperson - Second intergovernmental meeting of experts aimed at finalizing a draft declaration on universal norms on bioethics, 20-24 June 2005.

that restricts the concept to the ethical issues arising from medicine and life sciences.

This basic divergence permeates the entire text of the draft declaration but it shouldn't be irresolvable. The Chair hopes that it could be dealt with in the use of terms and scope articles, therefore facilitating the negotiation of the remaining articles.

**In that spirit:**

- a. Would it be acceptable not to have a definition of bioethics as presently contained in article one?
- b. Would the merger of articles 1 and 2 be acceptable?
- c. Would the concept of description rather than definition be acceptable?
- d. If the answer to the three previous questions is yes: Can we focus in the new article onto what and to whom the declaration applies?
- e. If so, and in reference to whom it applies, the Chair believes that some formulations based on the States as primary objectives of the Declaration and other actors as secondary recipients in a more residual capacity as appropriate, could be a possible compromise.
- f. As to the 'what': As bioethics does not evolve in a vacuum, can we include a contextual reference to social issues and the biosphere there?

- g. Would it be possible to drop definitions of 'decisions and practices' at this stage and come back to using these terms on a case by case basis, when they are applicable in other parts of the draft declaration?

The ensuing discussion of these questions informed the final text of Article 1, which was based largely on proposals made by the representative of Germany and delegate from Peru.<sup>15</sup> Thus, the adopted text in October 2005 was as follows:

***Article 1 - Scope***

- 1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.*
- 2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practises of individuals, groups, communities, institutions and corporations, public and private.*

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<sup>15</sup> Report of Second Intergovernmental Meeting of Experts aimed at finalising the draft Declaration, 20-24 June 2005.

Comment on the history of the text

The text of Article 1, as adopted by the Thirty-third Session of the General Conference of UNESCO in October 2005, is different from the text proposed in January 2005 by the International Bioethics Committee of UNESCO (IBC).

As finally recommended by the IBC, the Draft Declaration included a definition of "bioethics". It also included a definition of "decision" and "practice", that being the language in which each of the "principles" of the Draft Declaration was then expressed. The IBC Drafting Group, and eventually the IBC, accepted that language in the expressed hope of rendering the Principles of the Declaration more concrete, such that they would be enlivened in each case by "decisions" and "practices" of bioethical relevance, wherever arising. In meetings of inter-governmental experts, designed to ensure the acceptability of the proposed Declaration, to the Member States of UNESCO, in advance of its consideration at the General Conference, the repeated reference to "decision" and "practice" throughout the Principles was deleted. In harmony with the belief of many Member States that the Principles should be expressed in more general terms and shall avoid the use of mandatory verbs ("shall", "must") the Principles were restated as they now appear. Mandatory verbs were replaced by verbs thought more appropriate to the non-binding nature of the Declaration. Thus, "should" and "is/are to be" were

substituted. The mandatory expression "shall" was retained only in Arts 25.1 and 25.2 of the Declaration.

The consequence of this radical change to the IBC draft was to alter the format of the expression of the Principles throughout the Declaration. It thus removed the perceived need for a definition of "Bioethics" and of decisions or practices within the scope of the Declaration. Reference to the scope and to "decisions or practices" was retained in the opening words of the section of the Declaration containing "Principles". As adopted, this reads:

*"Within the scope of this Declaration, in decisions or practises taken or carried out by those to whom it is addressed, the following Principles are to be respected".*

By these changes, the general provisions of the Declaration on "Scope" were separately altered. Nevertheless, because of the substituted opening words of the statement of the Principles of the Declaration, identification of its "Scope" is important. Hence the significance of Article 1.

#### Interpretation of the text

The Declaration is not a treaty, open to subscription and ratification by Nation States or international organisations. It is not, therefore, as such, rendered part of international law by its adoption by the General Conference of UNESCO. As a matter of international

law, such adoption does not bind the Member States legally to conform to the provisions of the Declaration. To the extent that the Member States assume some obligations and responsibilities under the Declaration, these are expressed in terms of the language of its provisions and, in particular, the terms of Arts 22, 23 and 24 of the Declaration concerning the role of States, their participation in bioethics education, training and information sharing and their encouragement of international cooperation in this respect. Arts 22, 23 and 24 are expressed by reference to the non-mandatory verb "should". Additionally, the Principles themselves, also being expressed in non-mandatory language, make clear the content of the State responsibilities assumed by participation in the decision of the General Conference to adopt the Declaration. The Declaration is hortatory, aspirational and educational rather than legally normative.

Nonetheless, in giving meaning to the provisions of the Declaration, it may be assumed that its provisions would be interpreted in a manner analogous to the way in which treaties are interpreted in international law. It is therefore useful to have regard, by analogy, to the *Vienna Convention on the Law of Treaties* ("The Vienna Convention"). Article 31 of that Convention contains general rules of interpretation. Those rules substantially collect and express the proceeding principles of customary international law. The primary rule (Art 31.1 of the Vienna Convention) is that such instruments are to be "interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the Treaty in their

context and in the light of its object and purpose". The reference to the "purpose" permits regard to be had (Art 31.2) to a Preamble admissible travaux preparatoires. The context is also to be taken into account including any subsequent agreement regarding interpretation; any subsequent practice which establishes agreement about interpretation; and any relevant rules of international law (Art 31.3).

Different approaches to interpretation of texts in municipal and international law have coalesced in recent times in many legal systems towards a "purposive" construction of written language, taking into account its purpose and context. The interpretation gives primacy to the written text. However, context, object and purpose are also considered in producing a "holistic" interpretation of its language. In the past, at least in common law countries, this produced a more liberal approach to interpretation than was typical in the approach of municipal courts to discerning the meaning of domestic legal texts which tended to be read more narrowly or literally. However, recent shifts in many common law countries away from strict literalism and towards purposive construction, have reduced the previous distinctions between the approaches to interpretation adopted in municipal and international jurisdiction<sup>16</sup>.

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<sup>16</sup> Reports of the International Law Commission to the General Assembly [1966] 2 *Yearbook of International Law Commission* 169 at 218-220; I Brownlie, *Principles of Public International Law* (4th ed, 1990), 628.



This said, differences remain. Because international instruments are often drafted in multiple languages, involve input from experts of differing legal traditions and cultures and reflect many compromises and trade-offs in the process of negotiation, international texts, such as the Declaration, still require a generous approach to interpretation in order to ensure that they carry into effect the imputed intention of those who adopted them. It may be inferred that this is especially so where the text expresses not a binding treaty but principles or guidelines designed to promote identified objectives and to point the various readers in directions considered desirable.

Nowhere is the need for a broad and liberal approach to construction more necessary than in general provisions of a non-binding international Declaration that express the ambit, purpose and intended operation of the Principles thereafter appearing. This is why, it is customary and useful to have regard in the ascertainment of the imputed purpose, to such background materials as the travaux préparatoires contained in the record of the debates leading to the adoption of the Declaration. Such sources, whilst helpful, should not distract attention from "the primary source of ... interpretation"<sup>17</sup>. This remains a textual analysis. In the event of a conflict between the text and the apparent intention, purposes or

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<sup>17</sup> *Golder v United Kingdom* (1975) 1 EHRR 524 at 544-547 per Zekia J.

wishes of the drafters, the duty of the interpreter is ultimately to the text, read as a whole and in the context of other relevant laws and principles. Against this background the following remarks may be made on the text of Article 1 of the Declaration (Scope).

#### Textual analysis

*"This Declaration"*: This phrase is a reference to the *Universal Declaration on Bioethics and Human Rights*, adopted by the General Conference of UNESCO in October 2005.

*"Addresses"*: This is a word connoting the use of formal writing directed to identified persons or issues. The use of the verb "addresses" in Art 1.1 is to be contrasted to the form appearing in Art 1.2 ("is addressed to"). No significance appears in the different language chosen in the two sub-articles. The words used in each sub-article express a factual feature of the Declaration. However, because the "Scope" can, by the preambular words in the Statement of Principles, affect the application of the Principles to particular decisions of practices, the factual statement takes on a normative flavour.

"Ethical issues": This expression is not defined in the Declaration. The IBC Draft of the Declaration included a definition of "bioethics" as<sup>18</sup>:

*"The systematic, pluralistic and inter-disciplinary study and resolution of ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications".*

The deletion of "social" sciences appears to be deliberate and designed to limit the scope of the ethical issues addressed by the Declaration. In this context "ethical" means pertaining to, or dealing with, right and wrong in conduct, ordinarily in accordance with rules or standards for judging what is right or wrong conduct or practice. Note, also, that the language of Art 1.1 deletes reference to the relationship of human beings with the biosphere and to the availability and accessibility of scientific and technological developments and their applications. The reference to the biosphere elsewhere in the Declaration as adopted (notably in the provisions of Art 17 ("Protection of the Environment, the Biosphere and Biodiversity")) means that, by this express provision, the Declaration addresses issues of the biosphere as there specifically provided. However, the deletion of the reference from the terms of Art 1.1 in the Statement of the Scope of the Declaration has the effect that

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<sup>18</sup> IBC final Draft, Art 1 para (i).

other principles, apart from Art 17, need not be interpreted, without clear warrant in the text, as applying to the role of human beings in the protection of the biosphere.

*"Related to"*: These words are generally taken as words of the widest connection. Similarly, "issues" is a word of wide connotation. Accordingly "issues related to medicine, life sciences and associated technology" is a very broad expression, apt to a definition of the "Scope" of a Declaration. The provision is designed to confine the "ethical issues" subject to the Declaration to those identified. Thus, ethical issues related to philosophy, law and the social sciences, as such, are not included in the scope of the Declaration unless, in the particular case, they are "related to" the disciplines and developments mentioned in Art 1.1. The word "medicine" would usually connote therapeutic and other means addressed to the benefit of human beings and other higher forms of life. The phrase "life sciences" on the other hand is focussed more generally. It denotes the sciences that study living matter in all of its variety, including where it manifests itself in primitive and rudimentary forms. However, the width of this focus is potentially cut back by the reference to application "to human beings".

*"As applied to human beings"*: The Draft is not clear whether this phrase qualifies "Associated Technologies" or the entire preceding expression "Medicine, Life Sciences and Associated Technology". Given the context, it appears likely that the drafters

intended the necessity of application to human beings as a requirement for each of the Ethical Issues in Art 1.1. To this extent, the Draft incorporates an anthropomorphic view of the scope of the Declaration.

*"Taking into account their social, legal and environmental dimensions"*: This phrase appears to be a corrective against any narrow view of the words "human beings". In short, the application to "human beings" is not confined to medical aspects of human life presenting ethical issues. In the past, this has often been the traditional area of bioethical discourse. It has been one substantially dominated by the healthcare professions. The inclusion of the social, legal and environmental dimensions of human beings broadens this more traditional focus of bioethics. Specifically, the reference to "legal ... dimensions" incorporates reference to international law, specifically international human rights law. Whilst some traditional commentators, yearning for the maintenance of a medical model of bioethics, have criticised "the confusion of law and ethics that permeates the document", the adoption in the Scope of the Declaration of an approach that that combines the previous medical and scientific concerns about bioethics with the principles of international human rights law, is a deliberate one. It was a major objective of the IBC and its drafting group. The reference to "social, legal and environmental dimensions" is obviously designed as a corrective to an overly narrow view of the scope of the Declaration as applicable only to medical, life sciences and associated

technologies applicable to human beings. In particular, the reference to "social" emphasises the social characteristics of human beings in which ethical issues can arise in their relations with other human beings, with other life forms and with the environment.

Several of the Principles of the Declaration that follow the General Provisions are concerned with aspects of the "legal ... dimensions". These include Art 3 ("Human Dignity and Human Rights"), Art 5 ("Autonomy and Individual Responsibility") and Art 10 ("Equality, Justice and Equity"). The "social ... dimensions" are also referred in several Principles including in Art 12 ("Respect for Cultural Diversity and Pluralism"), Art 13 ("Solidarity and Cooperation") and Art 14 ("Social Responsibility and Health"). The "environmental dimensions" are the specific focus of Art 17; but they are also referred to by implication in Art 16 ("Protecting Future Generations").

#### Art 1.2

*"This Declaration"*: This is a reference to the *Universal Declaration on Bioethics and Human Rights*, adopted by UNESCO in October 2005.

*"Is addressed to States"*: This expression makes it clear that the primary addressees of the Declaration are the Nation States that are members of the international community, specifically of UNESCO whose Declaration this is. In a sense, this is a statement of the

obvious. The character of the Declaration as an instrument of an international organisation made up of Member States of the United Nations, makes it inevitable that the instrument should be addressed to those who make it and give it such force and application as it enjoys. One object of the previous manner of drafting the Principles, contained in the IBC Draft, was to afford a statement of principles that would influence "any decision or practice" having bioethical application or relevance. The deletion of this approach by the inter-governmental meeting of experts, representing Member States of UNESCO, altered the focus of the instrument and emphasised its purpose as being to address States, as such, and to recommend a role for them in giving effect to the Principles (Art 22); in fostering relevant education, training and the exchange of information (Art 23) and in promoting international cooperation in scientific and technological knowledge (Art 24).

*"As appropriate and relevant"*: In the ensuing elaboration of the obvious fact that the Declaration provides guidance for the decisions and practices of recipients other than States, the Declaration omits a precise identification of the ambit and occasions in which such guidance will be given beyond that specifically addressed to States. No detail or elaboration is afforded of when it will be "appropriate and relevant" to read the Declaration as providing guidance beyond nation States. One view would be that it is for the States themselves to so decide, by the adoption of their own municipal laws and policies. Another view, which seems the

preferable one, is that it is left within the States to the natural and legal persons identified to decide to what extent the Principles in the Declaration are "appropriate and relevant" for their "decisions or practices".

Given that the Declaration purports to state general principles in language that is not mandatory in its expression, the reference to "natural and legal persons" and the use that they may make of the Declaration simply recognises, as is stated, that the Principles are to be respected in decisions or practices taken or carried out "by those to whom it is addressed". This leaves the addressee of the Declaration to be identified from the language of the particular Principles or from other contextual considerations.

*"Provides guidance to decisions or practices":* The reference to "decisions or practices" was formerly a repeated operative phrase in the IBC Draft of the Declaration. Although it has been removed as a common expression in the statement of each of the Principles, the reference is retained in Art 1.2 and in the preambular words before the statement of the principles in Arts 3-17. The reference to "decisions" is a reference to individual choices made in the particular instances or circumstances to which the Declaration is addressed, and in particular in the Principles themselves. The reference to "practices" is a reference to standards of conduct and regular modes of addressing "decisions" of the kind described.



*"Of individuals, groups, communities, institutions and corporations, public and private"*: The range of natural and legal persons brought within the scope of the Declaration is extremely wide. It includes natural persons ("individuals") and legal persons ("groups, communities, institutions and corporations"). Note that elsewhere in the Declaration collective expressions appear which are not exactly the same as the collection in Art 1.2. Thus in the eleventh paragraph of the Preamble, reference is made to the benefits of science and the promotion of the welfare of "individuals, families, groups or communities and human-kind as a whole". In the thirteen paragraph of the Preamble, reference is made to the impact of decisions on ethical issues "on individuals, families, groups or communities and human-kind as a whole". This collection of interested subjects is not repeated in the substantive paragraphs of the Principles. See Art 1.2, 2(b) and compare the specific focus mentioned in the Principles stated in Arts 11 ("no individual or group"); Art 14.2(a) ("women and children"); Art 16 ("future generations") and Art 17 ("human beings ... the environment, the biosphere and biodiversity").

*"Application of the provision"*: The provisions of Art 1 identify the intended scope of the Declaration. However, as it plain from Art 1.2, it is largely left to the nation States which adopted the Declaration at the General Conference of UNESCO, acting through their ordinary procedures of law and policy making, to decide the extent to which (if at all) they will give effect to the Declaration and

its Principles. Similarly, it is left to individuals and the nominated groups within the nation State to decide the extent to which (if at all) they will, in their "decisions or practices" accept and implement the Principles in the Guidelines as affording guidance to themselves. States have no legal duty to implement the Guidelines. This is made clear by the use of the non-mandatory expression "should take all appropriate measures" in Art 22.1. Nevertheless, because the Declaration was adopted unanimously by the General Conference on UNESCO, without any State recording its dissent, reservation or qualification, it may be assumed that the participating States accepted the Declaration, as they did, in good faith and with the intention of following up its provisions in such ways, and at such time, as seems suitable to them. Because of the non-mandatory language in which the Principles themselves are stated ("should")<sup>19</sup>, ("is/are to be")<sup>20</sup>, ("is")<sup>21</sup> and ("may")<sup>22</sup>, the carrying into effect of the Principles, whether at the State level or at the level of decisions and practices of natural or legal persons, is left to the State and to the individuals or legal persons concerned.

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<sup>19</sup> Arts 3.2, 4, 6.1, 6.2, 6.3, 8, 9, 11, 12, 14.2, 15.1, 15.2, 16, 18.1, 18.2, 18.3, 19, 20, 21.1, 21.2, 21.3, 21.4, 21.5, 22.1, 22.2, 23.1, 23.2, 24.1, 24.2, 24.3, 27.

<sup>20</sup> Art2 3.1, 5, 6.1, 7, 10, 13, 17 and 26.

<sup>21</sup> Arts 14.1, 28.

<sup>22</sup> Art 6.3.

*"Illustrations":* The Scope of the Declaration is important for all that follows. In particular instances, where the State or an individual or legal person, are considering whether, for particular bioethical decisions, useful guidance is afforded by the Declaration, instances may arise where the Principles themselves are ambiguous because of the general language appearing in particular provisions.

In such instances, it may be useful for the decision-maker to have regard to the statement of the intended scope of the Declaration contained in Art 1. Thus, for example, the Declaration is not a general statement governing decisions of concern to the environment, the biosphere and biotechnology. On the other hand, such considerations are mentioned, notably in Art 17. To decide whether, in the particular case, the General Principles of the Declaration apply to a matter affecting the biosphere or the environment, guidance can be derived from the provisions as to Scope. These provisions make it clear that the primary focus of concern of the Declaration is generally upon the impact on ethical decision-making of medicine, life sciences and associated technologies as applied to human beings. Whilst that application is expanded by the reference to the "social, legal and environmental dimensions" of human beings, the stated provision as to Scope suggests that more general ethical questions concerning biodiversity, animal welfare and the environment will need to be addressed in further, more specific and detailed instruments that are more directly addressed to such concerns.

This said, the specific acknowledgment in Art 1.2 that "as appropriate and relevant" the Declaration provides guidance to decisions or practices by natural and legal persons, beyond the State, signifies the wide potential operation of the Declaration. An objective of the IBC, in its formulation of the Principles, was to state general principles in a manner that would permit them to be identified, to stand alone, so that they could be available at the work desk, in the laboratory, for the boardroom and elsewhere where ethical questions presented by any aspect of biology arose to be decided. They would thus afford the decision-maker a check-list of principles. Whilst the formulation of the Principles has been changed by the inter-governmental experts, the broad focus adopted in Art 1.2 indicates that the General Conference of UNESCO preserved the overall intention of the IBC that the Declaration should have a broad operational and educative effect. It is not, as such, wholly dependent on initiatives of law or policy-making taken by Member States. It is addressed, by its terms, in language that may be utilised by relevant decision-makers, including individuals, and in families and groups and communities when faced with dilemmas of bioethical concern. To this extent, the Declaration as adopted carries forward the broad objective of the IBC and its Drafting Group.