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NATIONAL LEGISLATION CONCERNING HUMAN REPRODUCTIVE AND THERAPEUTIC CLONING

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Division of the Ethics of Science and Technology

* This document will be periodically revised. Any information on relevant laws and regulations that could assist in updating this document should be addressed to the Division of the Ethics of Science and Technology (fax.33(0)1 45 68 55 15, e-mail: o.ikebe@unesco.org).

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1. INTRODUCTION

Following the first successful birth of a cloned mammal, Dolly the sheep, in 1997, the international community became seriously concerned about the application of cloning technique to human beings. Responding to such public fears, certain countries rapidly moved to prohibit human reproductive cloning, whether by official statement, decree or law.

At the international level, the Universal Declaration on the Human Genome and Human Rights was adopted unanimously and by acclamation by the General Conference of UNESCO in 1997 and endorsed by the General Assembly of the United Nations in 1998. It is the first international instrument to condemn human reproductive cloning as a practice against human dignity. Article 11 of this Declaration states: “*Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected*”.

At the regional level, the Additional Protocol to the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings was introduced in 1998 and came into force on 1 March 2001. Article 1 of the Protocol states: “*Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.*” This Protocol has been ratified by Croatia, Cyprus, Czech Republic, Estonia, Georgia, Greece, Hungary, Lithuania, Republic of Moldova, Portugal, Romania, Slovakia, Slovenia and Spain, and is awaiting ratification by 31 other countries.

At the national level, however, only about 30 countries have adopted national legislation or decrees that explicitly or implicitly prohibit the reproductive cloning of human beings. About 20 other countries are preparing or reviewing legislation with the same goal. Although different positions exist concerning the regulation of cloning techniques employed for therapeutic purposes, there is no country which permits the practice of human reproductive cloning. It is clear that an international consensus rejecting human reproductive cloning under current circumstances has emerged. Further implement this consensus position into national legislation, however, remains a primary goal.

This document was drafted in order to provide Member States with an overview of existing national legislation concerning human reproductive and therapeutic cloning. This information is intended to assist countries considering the introduction of such legislation where none yet exists.

WHAT IS CLONING?

“Cloning” is a technology which has been widely employed in the field of biology to produce genetically identical cells, tissues or whole organisms of plants or animals. In the existing legal texts concerning human cloning, reference is made to techniques to create artificially an embryo, fetus or individual that is genetically identical to another embryo, fetus or individual alive or dead.

Currently, two methods to create genetically identical mammals are known: Embryo splitting and somatic cell nuclear transfer (SCNT). Embryo splitting is the separation of cells of the embryo at a very early stage of development into two or more before their implantation into a uterus. The separated cells each develop into a complete organism which is genetically identical to the others. This sometimes happens spontaneously resulting in identical twins. Somatic cell nuclear transfer, on the other hand, is an attempt to create embryos asexually. The nucleus of a somatic cell will be inserted into an enucleated egg instead of fusion of male and female gametes. Therefore, the embryo created in this way is genetically almost identical to the donor cell of the nucleus.

WHAT IS REPRODUCTIVE CLONING AND “THERAPEUTIC” CLONING?

One of the possible reasons to create genetically identical embryos is to implant such embryos into a uterus so that a baby carrying the identical genetic characteristic to another person will be born. This is often referred to as “Reproductive Cloning”.

The objective of so-called “Therapeutic Cloning” on the other hand is to create a clone embryo by SCNT that would be used for therapeutic purposes such as deriving embryonic stem cells without generating a pregnancy. The potential of therapeutic cloning has been the issue of intense discussion within the international community as one possible way to produce cells, tissues or organs that are genetically compatible with patients to treat diseases and physical injuries. For this purpose, the nucleus of a somatic cell of the patient would be transferred into an unfertilised enucleated egg and be developed to an embryo. In the course of derivation of stem cells, the embryo would be destroyed. Since the therapeutic potential is unclear at the moment, it is better to speak of “research” cloning rather than “therapeutic” cloning.

REGULATIONS OF REPRODUCTIVE CLONING

At present, there is no country which permits reproductive cloning of human beings by legislation or guidelines. Concerning the prohibition of this practice, three approaches appear in existing national legislation as follows:

1. Prohibit the creation of clone embryo (by embryo splitting or by somatic cell nuclear transfer);

2. Prohibit the implantation of a clone embryo into a uterus;
3. Without specifying the method, prohibit any attempt to artificially create a human being genetically identical to another human being (embryo or fetus) alive or dead.

REGULATIONS OF “THERAPEUTIC” CLONING

Concerning therapeutic cloning on the other hand, different positions and regulations are observed in various national legislation. Regulations on SCNT for embryo creation are rarely mentioned in the legal text but creation of such embryos are generally regulated under embryo research. Currently, there exist three different positions on embryo research:

1. Generally prohibit research on embryos (with some specific exceptions) and/or creation of embryos for research purposes;
2. Permit research on supernumerary embryos produced by fertility treatment but prohibit creation of embryos for research purposes;
3. Permit creation of embryos for research purposes with strict conditions.

Positions 1 and 2 are interpreted as prohibiting therapeutic cloning and position 3 is understood as possible permission for therapeutic cloning depending on the conditions provided for embryo research. Nevertheless some ambiguity persists in position 1 when exceptions to the prohibition on embryo research are provided for the purpose of “research for preventing or treating diseases” or “research for therapeutic purposes”. Some countries read this exception as permission for therapeutic cloning. Certain countries are reviewing and amending such text in the existing legislation to clarify the position on therapeutic cloning. For example, Act 460 on Medically Assisted Procreation of 1997 in Denmark clearly forbids therapeutic cloning by forbidding research on SCNT. In contrast in 2001, the UK amended The Human Fertilisation and Embryology Act of 1990 to clarify the position favourable towards therapeutic cloning by including reasons for granting the creation of embryos for research purposes such as “to increase knowledge about the development of embryos and about serious disease and to enable any such knowledge to be applied in developing treatment for serious disease.”

Further efforts to clarify the national position on therapeutic cloning by reviewing or amending existing legislation should be encouraged since this technique is relatively new and some legislative texts do not anticipate the application of such a technique.

2. OVERVIEW OF NATIONAL LEGISLATION

Following is an overview of existing national legislation, official guidelines and opinions as well as draft legislation currently under discussion which regulate the cloning techniques using human genetic materials.

ARGENTINA

By a decree of March 1997, the President of Argentina declared all cloning experiments in connection with human beings to be prohibited and requested that the Ministry of Health and Social Action prepare a draft bill to that effect. Three relevant bills, No. 100/03 (2003), No. 827/00 (2000), and No. 0269-D-01 (2001) are today before the national parliament. At the regional level, two provinces have enacted laws specifically prohibiting cloning experiments involving human beings and human reproduction through cloning within their territorial boundaries: one is law No. 6581 of 1998 in Mendoza province and the other is law No. 9072 of 2003 in Cordoba province.

AUSTRALIA

The Gene Technology Act 2000, which took effect in July 2001, prohibits “cloning of human beings” subject to criminal sanctions (section 192B). It defines cloning of a whole human being as “*the use of technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical to the original.*” At the state level, Victoria, Western Australia and South Australia have incorporated the regulations set out in the Gene Technology Act 2000 into their respective state laws.

Furthermore, the Prohibition of Human Cloning Act 2002 and Research Involving Human Embryos Act 2002 received Royal Assent on 19 December 2002 following the historical split of the bill in September. The human cloning ban applies to the creation of cloned embryos for reproductive and related purposes, to attempts to implant such an embryo into a uterus, and to their import and export.

“A person commits an offence if the person intentionally creates a human embryo clone. (Part 2, Division 1, Section 9)

A person commits an offence if the person intentionally places a human embryo clone in the body of a human or the body of an animal. (Part 2, Division 1, Section 10)

A person commits an offence if the person intentionally imports a human embryo clone into Australia. (Part 2, Division 1, Section 11(1))

A person commits an offence if the person intentionally exports a human embryo clone into Australia. (Part 2, Division 1, Section 11 (2))”

All offences under this ban are punishable by up to 15 years’ imprisonment.

AUSTRIA

The Law on Medically Assisted Human Reproduction was passed in July 1992, implicitly prohibiting the cloning of human beings. Article 9 states that fertilized human oocytes and cells

derived therefrom may not be used for other purposes than medically assisted reproduction; and any intervention into the germ-line is strictly prohibited. Any violation or attempt at violation is subject to administrative or criminal prosecution.

BELGIUM

The Law of 11 May 2003 concerning research on embryos in vitro states in Article 6: “*Human reproductive cloning is prohibited*”. Article 3 allows research on embryos in vitro for therapeutic purposes as well as for scientific research only where no other method of comparable efficacy is available and under strict conditions, notably if research takes place in accredited university laboratories with local and federal oversight on embryos within their first 14 days of development. Article 4 prohibits the creation of embryos for research purposes, except where supernumerary embryos will not meet research objectives, and subject to the same strict conditions applicable to embryos in vitro under Article 3.

BRAZIL

Article 8 of Law 8.974 of 1995 on the Uses of Genetic Engineering Techniques and Release of Genetically Modified Organisms into the Environment expressly prohibits the genetic manipulation of human germinal cells and intervention in *in vitro* human genetic material. Exemptions may apply to therapeutic purposes and the treatment of genetic diseases, subject to certain ethical considerations and prior governmental approval. After a thorough analysis of the law, the Brazilian Biosafety Technical Commission of the Ministry for Science and Technology issued two normative instructions in 1997 to clarify the intended ban on human reproductive cloning, specifically stating that genetic manipulation of human germinal cells includes the nuclear transference technique.

CANADA

Act Respecting Assisted Human Reproduction and Related Research (Assisted Human Reproduction Act) prohibiting reproductive and therapeutic cloning was adopted in March 2004. Article 5 states: “*No person shall knowingly (a) create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device; (b) create an in vitro embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures; (c) for the purpose of creating a human being, create an embryo from a cell or part of a cell taken from an embryo or foetus or transplant an embryo so created into a human being;*” However, the research on embryos will be controlled under regulations and a licence which may open the way to conduct embryonic stem cell research with certain conditions such as using supernumerary embryos.

CHILE

Bill No. 1993-11 concerning scientific research on human beings, the human genome and banning human cloning has been introduced. It prohibits the cloning of human beings as well as

any intervention which results in the creation of a human being genetically identical to another, dead or alive.

CHINA

The Ministry of Public Health released “Rules on Assisted Reproductive Technologies for Human Beings” in August 2003, which went into force in October 2003. The regulations prohibit human reproductive cloning stating that “the performance of cytoplasm transfer and germinal vesicle transfer for infertility treatment is forbidden and the (reproductive) cloning of human beings is forbidden (para 3.7 and 3.15).” At the same time, the Ministry of Health released “Ethical Principles on Assisted Reproductive Technologies for Human Beings and Human Sperm Bank” in August 2003, which also entered into effect in October 2003. It is stated that “cytoplasm transfer and germinal vesicle transfer should not be allowed for infertility treatment before the problem of safety is resolved (Para 1.3.g)” The guidelines allow cloning research for therapeutic purposes.

In Hong Kong, Human Reproductive Technology Ordinance was enacted in June 2000. Section 15 of the Ordinance states: “*No person shall – (...) (a) for the purposes of embryo research - (i) bring about the creation of an embryo; (e) replace the nucleus of a cell of an embryo with a nucleus taken from any other cell; (f) or clone any embryo.*”

COLOMBIA

Law 599 of 2000 applies criminal sanctions to genetic manipulation and limits human embryo fertilization and traffic. Genetic code manipulation in certain fields may be exempt from this ban under specified conditions when carried out with the aim of research into the genetic diseases or disabilities. The fertilization and traffic in human embryos for purposes other than human procreation is otherwise strictly prohibited, as is traffic in gametes and zygotes. Several bills which may expand or modify this legislation are currently before the national congress.

COSTA RICA

Decree No. 24029-S - A Regulation on Assisted Reproduction of 3 February 1995, prohibiting all forms of manipulation of genetic codes of embryos as well as experiments on embryos in its Article 11, implicitly prohibits therapeutic and reproductive cloning.

DENMARK

Under Act 503 on a Scientific Ethical Committee System and the Handling of Biomedical Research Projects of 1992, research on cloning (production of genetically identical individuals) is forbidden. Act 460 on Medically Assisted Procreation of 1997 further forbids research on human reproductive cloning and somatic cell nuclear transfer (therapeutic cloning). The 1997 Act was amended in June 2003 by Act 427, allowing research for therapeutic purposes for supernumerary embryos from IVF treatment and derived stem cells. All such research requires prior approval under the established committee system.

EGYPT

A draft law addressing human reproductive cloning practices is currently under consideration. In conformity with a report produced by Islamic Research Academy, Egyptian authorities have issued an opinion strictly prohibiting experimental research on human reproductive cloning and allowing research into cloning of human tissues and cells for therapeutic purposes, as long as human rights and dignity are respected.

FINLAND

Under the Finnish Medical Research Act (488/1999), research with the aim of cloning human beings is prohibited (section 26), as is the production of embryos exclusively for research purposes (section 13). Research on embryos and gametes in order to modify hereditary properties is also prohibited, unless the research is aimed at curing or preventing a serious hereditary disease (Section 15). The existing act has been interpreted as allowing therapeutic cloning under the conditions set forth therein (sections 11-13). Those found in violation face fines or imprisonment.

FRANCE

At the request of President Chirac, the National Consultative Ethics Committee on Health and Life Sciences (CCNE), released its Opinion No. 54 of 22 April 1997 concluding that *“an attempt at identical reproduction of human beings whose genome would no longer be the result of the lottery of heredity and instead depend on another's will, would seriously endanger essential original indetermination as well as other fundamental traits of a person”* and called for global collaborative efforts against reproductive cloning.

In July 1994, the Bioethics law which regulates practices in the fields of medicine, reproductive technologies, genetics and organ donation was adopted. Certain articles of the health code, penal code, intellectual property code and civil code relevant to the human body are included in the Bioethics law. In July 2004, the revised Bioethics law was adopted after a lengthy and intensive discussion. The new law explicitly prohibits human cloning both for reproductive and therapeutic purposes. Regarding reproductive cloning, Article 21 states: *“Any intervention designed to produce a child who is genetically identical to another person, dead or alive, is prohibited.”*

Therapeutic cloning is addressed as follows. Article 25: *“Any creation of a human embryo by fertilisation or by cloning for research purposes is prohibited. Creation of a human embryo by fertilisation or by cloning for commercial or industrial purposes is prohibited. Equally, any creation of a human embryo by cloning for therapeutic purposes is prohibited”*

With regard to research on embryos in general Article 25 also states that, *“Research on human embryos is prohibited.”* The Article then delineates very limited exceptions, including government authorized research carried out within five years from the date of entry into force of the law and only if the research is likely to lead to “major therapeutic progress” where no other available method “offers comparable effectiveness.” Nevertheless, this exception is only

permitted using embryos created *in vitro* for the purpose of procreation and which are no longer used for this purpose, given informed consent by the donors. In any case, such research requires authorization from the Agency of biomedicine established by this law.

GEORGIA

Section 142 of the Law of 10 December 1997 on Health Care states: “(1) *Human cloning through the use of genetic engineering methods shall be prohibited.* (2) *The State shall control research in the field of genetic engineering in accordance with the law.*”

GERMANY

The Embryo Protection Act 1990 explicitly prohibits attempts at human cloning for any purposes.

“Section 6

(1) *Anyone who causes artificially a human embryo to develop with the same genetic information as another embryo, fetus, human being or deceased person will be punished with imprisonment up to five years or a fine.*

(2) *Likewise anyone will be punished who transfers into a woman an embryo designated in paragraph 1.*

(3) *Any attempt is punishable.*”

The creation and utilization of embryos for any purpose other than reproduction is also prohibited under this law. However the Stem Cell Act (Stammzellgesetz) passed in 2002 permits the import of embryonic stem cells produced from supernumerary embryos that date before 1 January 2002 upon approval by a supervisory body.

GREECE

The General Council for Health Statement of 1988 explicitly prohibits reproductive cloning. The recently adopted law 3089/2002 on Medically Assisted Human Reproduction *inter alia* prohibits explicitly reproductive cloning by stating that “*human reproduction with the methods of cloning prohibited*”. According to this law, creation of embryos can be permitted only “*in order to treat the incapacity to have children by natural way or to avoid the transmission of a severe disease to the child*”. Nevertheless research on embryos using supernumerary embryos is allowed for therapeutic purposes.

ICELAND

Article 12 of the Act on Artificial Fertilization (55/1996) prohibits to:

- “a) cultivate or produce embryos solely for research purposes;
- d) perform cloning.

Research on embryos is generally prohibited by Article 11, with exceptions for “a) *if it is part of an in vitro fertilization treatment; b) if the intention is to diagnose hereditary diseases in the embryos themselves; c) if the purpose is to advance the treatment of infertility, or; d) if the*

purpose is to improve understanding of the causes of congenital diseases and miscarriages". Violators face fines or imprisonment.

INDIA

In 2000 the Indian Council of Medical Research issued a Consultative Document on Ethical Guidelines for Biomedical Research on Human Subjects. The section addressing genetics states: "*Since its safety, success, utility and ethical acceptability is not yet established, research on cloning [through nuclear transplantation or embryo splitting] with intent to produce an identical human being, as of today, is prohibited.*" Indian government's ethical policy document on the human genome, genetic research and services prohibits reproductive cloning, but opens the door to therapeutic cloning considered on a case-by-case basis by the National Bioethics Committee.

IRELAND

Ireland established a Commission on Assisted Human Reproduction in 2000 to report on the range of available means to regulate all aspects of assisted human reproduction, taking into account the relevant social, ethical and legal policy factors in that area. The commission, whose purview thus includes human cloning, is expected to publish its report.

ISRAEL

The 1999 Prohibition of Genetic Intervention Law (Human Cloning and Genetic Modification of Reproductive Cells Act) states that, during a period of 5 years, no act of intervention on human cells will be carried out, if the purpose of such intervention is either to clone a human being or to bring about the creation of a human being through the use of reproductive cells which have undergone a permanent intentional genetic modification. Any offence against this regulation is subject to imprisonment (Section 6). However, Section 5 sets forth a special exemption to this general prohibition: the Minister of Health may permit the creation of a human being through the use of genetically modified reproductive cells, if he finds that no harm will be caused to human dignity.

ITALY

Awaiting the approval of a controversial law on assisted reproduction, the Ordinance of 5 March 1997 on the prohibition of practices of human or animal cloning was enacted. It states: "*Any form of experimentation or intervention, however practiced, with the goal, even indirect, of human or animal cloning is prohibited*" (Article 1). The proposed legislation would include imprisonment of up to 20 years and heavy fines for "*anyone who realises a project which aims to obtain a human being from one starting cell, genetically identical to another human being, alive or dead.*"

JAPAN

The Law Concerning Regulation Relating to Human Cloning Techniques and other Similar Techniques was passed in November 2000 and took effect in June 2001. It prevents the birth of a cloned human by prohibiting transplantation of clone embryos to a uterus of a woman or an animal.

“No person shall transfer a human somatic clone embryo, a human-animal amphimictic embryo, a human-animal hybrid embryo or a human-animal chimeric embryo into a uterus of a human or an animal.” (Article 3)

The production of clone embryos and embryo research are regulated by the Guidelines in Relation to Handling of Specified Embryos, issued by the Minister of Education, Culture, Sports, Science and Technology. According to the guidelines released in December 2001 (Guidelines in Relation to Handling of Specified Embryos), research on embryos is allowed only using supernumerary embryos resulting from IVF treatment within the first 14 days of development. In July 2004, the Bioethics Committee of the Council of Science and Technology released a report, which concludes that the creation of embryos for research purposes including clone embryos should be permitted under strict conditions and creation of a monitoring system should be urged. Acting on this report, the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare will work towards revising current guidelines in this line.

KOREA (REPUBLIC OF)

Bioethics law strictly prohibiting reproductive cloning under any circumstances, subject to criminal sanctions for up to 10 years in prison, regulating embryonic stem cell research, and creating a national bioethics committee was approved by the National Assembly in late December 2003. According to the law, the creation of embryos for purposes other than infertility treatments is prohibited. Only supernumerary embryos produced for infertility treatments can be used for research. However, the government will approve limited research on somatic nuclear transfer based on the guidelines drawn up by the National Ethics Committees.

LATVIA

The Latvian Parliament passed the law on Sexual and Reproductive Health in January 2002 for an entry into force in July of that same year. Article 16 of the law prohibits human cloning, or the use of medical techniques to create a human being who is genetically identical to another, alive or dead. The Additional Protocol to the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings is currently awaiting ratification.

LEBANON

The Lebanese National Advisory Committee on Bioethics is presently preparing draft legislation to prohibit all human reproductive cloning.

MEXICO

The General Health Law of 7 May 1997 and its regulations in the field of research for health care provides articles which can be interpreted as implicitly prohibiting human cloning. For example, Article 100 of the law and Article 13 and 15 of the regulations state that the interest of human beings prevails over that of science; Article 319 of the law prohibit the trade of human organ, tissues and cells; Article 100 and 300 of the law, Article 14 and 36 of the regulations concerning the use of human organs, tissues and bodies, requires the express consent of the person involved for the research on human bodies, donation and transplant of organs; Article 330 of the law prohibits the use of embryonic tissues or foetal tissues for any purposes.

NETHERLANDS

The Embryo Act, which prohibits human reproductive cloning and strictly regulates research on embryos, was adopted in July 2002. The law allows for staggered dates for entry into force by section, to be determined by Royal Decree. Section 24(a), which shall lapse no longer than five years after entry into force, prohibits the creation or use of an embryo for research purposes other than the induction of a pregnancy. Section 24(f) prohibits performing procedures with gametes or embryos with a view to the birth of genetically identical human individuals. Violations are punishable by up to one year in prison or a fine.

Once Section 24(a) has lapsed, Sections 9, 24(b) and 11 shall apply, prohibiting the creation and use of an embryo specifically for scientific research, except where such research is reasonably likely to lead to new insights in the fields of infertility, artificial reproduction techniques, hereditary or congenital diseases or transplant medicine and can only be performed by making use of such embryos. The use of any such specially created embryo for non-reproductive purposes must be made available by “*adults who are capable of making a reasonable assessment of their interests in this regard.*” (Section 9 (1).)

NEW ZEALAND

The Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 provides temporary measures, pending the development of a comprehensive legislative scheme, to control the use of cloning procedures for reproductive purposes. Under this Act, a procedure such as reproductive cloning may not be authorized by the Minister of Health unless it satisfies the following conditions:

- (a) *the conduct of the procedure or class of procedure does not pose an unacceptable risk to the health or safety of the public;*
- (b) *any risks posed by the conduct of the procedure or class of procedure will be appropriately managed;*
- (c) *any ethical issues have been adequately addressed;*
- (d) *any cultural issues have been adequately addressed;*
- (e) *any spiritual issues have been adequately addressed.*

Two bills aimed at regulating assisted human reproduction were introduced in 1996 (The Human Assisted Reproductive Technology Bill [HART]) and in 1998 (The Assisted Human Reproduction Bill). However, given the rapid progress in scientific knowledge concerning assisted human reproduction, the Government has decided that updating is necessary and is currently developing a comprehensive framework for the regulation of human reproductive technologies. In 2001, the Government decided to amend the HART bill through a Supplementary Order Paper (SOP) referred to a select committee for public comment in May 2003. The Government's intent is for resulting legislation to be enacted in early 2004. This proposed legislation would provide a permanent legislative framework for human reproductive cloning, superseding the 2002 Act. The SOP prohibits cloning for reproductive purposes, but allows for therapeutic cloning, subject to further investigation and regulatory measures to be defined.

NORWAY

Chapter 3 of Law No. 56 of 1994 on the medical use of biotechnology prohibits research on embryos as well as the use of techniques aimed at the production of genetically identical individuals. In July 2002, the Government presented a bill to the Parliament proposing an explicit prohibition against the use of therapeutic cloning as a method to produce embryonic stem cells for medical research.

PANAMA

In May 2001, Panama established a National Commission on Biosafety and Bioethics, charged with the drafting of bills pertaining to genetic biosafety, therapy and cloning.

PERU

Article 7 of the General Health Law (No. 26842) of 20 July 1997 prohibits fertilization of human oocytes other than for procreation, as well as reproductive cloning of human beings. Peruvian Criminal Code Art. 234 makes any person employing any genetic manipulation technique for purposes of cloning a human being punishable by imprisonment from six months up to eight years.

PHILIPPINES

A draft Act Prohibiting the Cloning of Humans and Providing Penalties for Violations Thereof (2003) was filed at the Philippine House of Representative waiting to be reviewed and approved by the Congress and Senate.

PORTUGAL

On 1 April 1997, the National Council of Ethics for the Life Sciences (CNEV) adopted Opinion 21/CNEV/97 which states that "*the cloning of human beings, because of the problems it raises*

concerning human dignity, the equilibrium of the species and life in society, is ethically unacceptable and must be prohibited.”

RUSSIAN FEDERATION

In April 2002, the Law on the Temporary Prohibition of Human Cloning was adopted. Under this law, creation of “a human being, genetically identical to another one, dead or alive, by means of implantation of a human body cell into a female gamete preliminarily deprived of its nucleus” is subject to a temporary five-year ban. The law also forbids import and export of human clone embryos for the same period. Persons violating the law will be prosecuted under federal law. However, neither the Criminal nor Administrative Codes specify the punishment for cloning acts.

SINGAPORE

On 21 June 2002 the Bioethics Advisory Committee of Singapore (BAC) released a report on “Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning.” The BAC recommends a complete ban on reproductive cloning and would permit therapeutic cloning only under strict regulations. Recommendation 7 states:

“There should be a complete ban on the implantation of a human embryo created by the application of cloning technology into a womb, or any treatment of a human embryo intended to result in its development into a viable infant.”

The report also concluded that creation of human embryos either by IVF (In Vitro Fertilization) or by SCNT (Somatic Cell Nuclear Transfer) for research purposes can only be justified where (1) there is strong scientific merit in, and potential medical benefit from, such research; (2) no acceptable alternative exists, and (3) on a highly selective, case-by-case basis, with specific approval from the proposed statutory body.

On 18 July 2002, the government approved the BAC recommendations.

SLOVAKIA

Human reproductive and therapeutic cloning are prohibited according to the Health Care Act No. 277/1994 and the Slovak Penal Code.

The Health Care Act No. 277/1994 states:

“Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited” (Article 46).

Therapeutic cloning is implicitly prohibited by article 42, sub-paragraph 3 c of the same act which states: *“Research without medical indication is not permitted on human embryos and foetuses.”*

Furthermore, cloning of human being became subject of criminal sanction by the Slovak Penal Code when article 246a was introduced on 1 September 2003 which reads as follows:

“1) Any person who performs any intervention seeking to create a human being in any stage of development genetically identical to another human being, whether living or dead, shall be

sentenced from 3 to 8 years of imprisonment or shall be punished by a prohibition of activity or by a pecuniary penalty.

2) The perpetrator shall be sentenced from 5 to 12 years of imprisonment if he/she:

(a) commits the criminal offence referred to in paragraph 1 in the capacity of a member of an organised group;

(b) gains for himself/herself or for other person no noticeable profit.”

SPAIN

Chapter VI, Article 20 of Law 35/1988 concerning medically assisted human reproduction makes the creation of identical human beings by cloning, or any other technology for race selection purposes, a serious infringement on human rights, with criminal sanctions. It also prohibits any attempt to create embryos with or without fertilization, other than for the purpose of procreation.

SOUTH AFRICA

The Law on Human Tissue 1983 implicitly prohibits the cloning of human cells. Section 39A states: *“Notwithstanding anything to the contrary contained in this Act or any other law, no provision of this Act shall be so construed as to permit genetic manipulation outside the human body of gametes or zygotes.”*

In 1998, a bill calling for the prohibition of human cloning was submitted to Parliament. However, it was rejected by Parliament on the basis that the very same issue was to be addressed in the Draft National Health Bill which was scheduled to be tabled later that same year. At present, however, the bill is still awaiting review.

SWEDEN

Law 115 of March 1991 concerning measures for the purposes of research or treatment in connection with fertilized human oocytes implicitly prohibits embryo and oocyte cloning with criminal sanctions. It states that the purpose of experimentation shall not be to develop methods aimed at causing heritable genetic effects.

In December 2001, the Swedish Research Council declared that creating embryos through somatic cell nuclear transfer for therapeutic purposes *“can be ethically defensible”* but would first necessitate the formulation of a legal framework by the Swedish government.

SWITZERLAND

The Federal Constitution explicitly prohibits all forms of cloning. *“All forms of cloning and interference with genetic material of human reproductive cells and embryos are prohibited (Article 119, paragraph 2).”* The Federal Law on Medically Assisted Procreation of 1998 (SR.814.90) which took effect on 1 January 2001 explicitly prohibits embryo and oocyte cloning with criminal sanctions. In its message to Parliament in November 2002 regarding the law on

embryo research, the Federal Council indicated that Article 119, paragraph 2 of the Federal Constitution also bans therapeutic cloning.

THAILAND

The Medical Council of Thailand released the regulations on Human Cloning in June 2002 (No. 21/2544) which indicates the prohibition of reproductive human cloning. Furthermore, the Stem Cell Guideline produced in November 2003 by the Bioethics and Advanced Biomedical Research Project managed by the National Center for Genetic Engineering and Biotechnology (BIOTEC) and the National Health Foundation (NHF) also indicates the prohibition of reproductive human cloning.

TRINIDAD AND TOBAGO

Senate Bill No. 4 of 1999 – An Act Respecting Human Reproductive Technologies and Commercial Transactions Relating to Human Reproduction- explicitly prohibits human reproductive cloning. Article 3 of the bill states that: “*No person shall knowingly – a) manipulate an ovum, zygote or embryo for the purpose of producing a zygote or embryo that contains the same genetic information as a living or deceased human being or a zygote, embryo or fetus, or implant in a woman a zygote or embryo so produced (...)*”.

TUNISIA

At the request of the Minister of Health, the National Medical Ethics Committee examined the issue of cloning in 1997. Following initial discussions, the Technical Section of the Committee concluded that any technology of human cloning should be banned. It deemed the practice as undermining the field of human reproduction and the dignity of the human species, and an open door to all forms of abuse.

UNITED KINGDOM

The Human Fertilisation and Embryology Act 1990 defines an embryo as “a live human embryo where fertilisation is complete”. Following the decision of the High Court on 15 November 2001 that embryos created by cell nucleus replacement were not governed by this act, the Human Reproductive Cloning Act 2001 was enacted in December 2001. It explicitly prohibits reproductive cloning by stating that “*a person who places in a woman a human embryo which has been created otherwise than by fertilization is guilty of an offence.*”

However, in January 2002 the Court of Appeals overturned the High Court decision of 15 November 2001, ruling that clones produced by cell nuclear replacement can be classified as embryos, thus coming under the regulations of the Human Fertilisation and Embryology Act 1990 which allows creation of and research on embryos before the appearance of the primitive streak. Pursuant to the Act, a Code of Practice was produced by the Human Fertilisation and Embryology Authority, which permits embryo research for the following purposes:

- To promote advances in the treatment of infertility;

- To increase knowledge about the causes of congenital disease;
- To increase knowledge about the causes of miscarriages;
- To develop more effective techniques of contraception;
- To develop methods for detecting the presence of gene or chromosome abnormalities.

In 2001, new regulations were made to allow creation of embryo for the following purposes:

- To increase knowledge about the development of embryos;
- To increase knowledge about serious disease
- To enable any such knowledge to be applied in developing treatment for serious disease.

This amendment together with the decision of the Court in January 2002 therefore opened the way for the Human Fertilisation and Embryology Authority to require a license for therapeutic cloning.

UNITED STATES OF AMERICA

In late February 2003, the U.S. House of Representatives passed a bill that would ban human cloning for reproductive and therapeutic purposes. It would make it unlawful for anyone “*to perform or attempt to perform human cloning; to participate in an attempt to perform human cloning; or to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo.*” (H.R.534- Human Cloning Prohibition Act of 2003.) The bill would impose a prison sentence of up to 10 years for violators and fines beginning at \$1 million.

The proposed legislation, strongly supported by the Bush Administration, has been sent to the U.S. Senate and calendared for vote. It mirrors a previous bill passed by the House last summer but which failed to reach a vote in the Senate due to sharp disagreement, even within the parties, over the prohibition of therapeutic cloning. The new Senate majority leader, a Republican physician long opposed to the cloning of human embryos, is expected to push hard for passage of a complete ban on all forms of human cloning.

Eight states have passed laws explicitly prohibiting human reproductive cloning, five of which prohibit human cloning for any reason. At least 22 others have introduced bills that would outlaw the reproductive cloning of human beings.

URUGUAY

A draft law on human assisted reproduction (3181/2003) prohibits human reproductive cloning with criminal sanction. Article 20 states that a person who manipulates human cells or genetic materials by cloning in order to create an identical human being containing the progenitor’s same genetic heritage, or who implants such an embryo into a female womb will be sentenced to imprisonment for a period of two to six years. If one or more human beings are created by cloning, prison terms run from three to nine years.

VIET NAM

The Vietnamese government has issued a decree banning both human cloning and surrogacy, which took effect in May 2003.

3. SUMMARY OF THE NATIONAL LEGISLATION

Some countries have introduced, legislation regulating human cloning with explicit wording while others reviewed their existing national legislation and concluded that it can be interpreted as implicitly regulating of human cloning. A prohibition on genetic manipulation of embryos or germ-line intervention in medically assisted reproduction is interpreted as implicitly prohibiting human reproductive cloning.

In sum, 23 countries have adopted legislation which explicitly prohibits human reproductive cloning and seven other countries have interpreted their existing legislation as implicitly prohibiting human reproductive cloning. Three countries introduced a provisional moratorium for a limited period of time. Six other countries have furnished official guidelines or reports expressing official positions against reproductive cloning. 10 countries are currently drafting legislation for the same objective.

As to therapeutic cloning, two main categories of regulations of the creation of embryos for research purposes have emerged, either as implicitly or explicitly prohibiting or granting permission to perform therapeutic cloning. Five countries have adopted legislation which may allow for the creation of embryos for research purposes under strict conditions, possibly opening the way to creating an embryo by nuclear transfer. Four countries have published official guidelines or reports which support the possibility of therapeutic cloning research.

On the other hand, 15 countries have adopted legislation which prohibits the creation of embryos other than for the purpose of procreation or for research which results in destruction of embryos. Official guidelines setting forth similar regulations prohibiting the creating embryos for research purposes have been published in one country.

Eight countries are currently preparing or reviewing legislation concerning therapeutic cloning or the creation of embryos for research purposes. In some cases, however, sharp disagreement over the potential of therapeutic cloning hinders the adoption of such legislation.

In conclusion, relatively few countries regulate on reproductive and therapeutic cloning. The debate concerning a regulatory framework at the national level should be further encouraged.

Annex: OVERVIEW OF NATIONAL LEGISLATION CONCERNING HUMAN REPRODUCTIVE AND THERAPEUTIC CLONING

COUNTRY	Reproductive Cloning				Therapeutic Cloning				
	Prohibition		Moratorium	Under Discussion	Prohibit the Creation of Embryos for Research Purposes		Possible Permission for Creation of Embryos for Research Purposes		Under Discussion
	National Legislation	Governmental Guidelines, Opinion	Legislation, Decree, Ordinance	Draft Law	National Legislation	Governmental Guidelines, Opinion	National Legislation	Governmental Guidelines, Opinion	Draft Law
Argentina	Decree of March 1997			No. 100/03 (2003), No. 827/00 (2000), No. 0269-D-01 (2001)					
Australia	The Gene Technology Act 2000, The Prohibition of Human Cloning Act 2002								
Austria	*The Law on Medically Assisted Human Reproduction (1992)				The Law on Medically Assisted Human Reproduction (1992)				
Belgium	The law concerning Research on Embryos in Vitro (2003)						The law Concerning Research on Embryos in Vitro (2003)		
Brazil	*Law 8.974 on Uses of Genetic								

* This legislation implicitly prohibits reproductive cloning of human beings

	Engineering Techniques and Release of Genetically Modified Organisms into the Environment (1995)								
Canada	Assisted Human Reproduction Act (2004)				Assisted Human Reproduction Act (2004)				
Chile				Bill No. 1993-11 Concerning Scientific Research on Human Beings					
China		Rules on Assisted Reproductive Technologies for Human Beings (2003), Ministry of Public Health: Ethical Principles on Assisted Reproductive Technologies for Human Beings and Human Sperm Bank (2003), Ministry of Health		Bill Human Reproductive Technology (1998)				Rules on Assisted Reproductive Technologies for Human Beings (2003), Ministry of Public Health: Ethical Principles on Assisted Reproductive Technologies for Human Beings and Human Sperm Bank (2003), Ministry of Health	Bill Human Reproductive Technology (1998)
Colombia	*Law 599 of 2000				Law 599 of 2000				

* This legislation implicitly prohibits reproductive cloning of human beings

Costa Rica	*Decree No. 24029-S				Decree No. 24029-S				
Denmark	Act 503 on a Scientific Ethical Committee System and the Handling of Biomedical Research Projects (1992), Act 460 on Medically Assisted Procreation (1997)				Act 460 on Medically Assisted Procreation (1997)				
Finland	Medical Research Act (488/1999)						Medical Research Act (488/1999)		
France	Bioethics Law (2004)				Bioethics Law (2004)				
Georgia	Law on Health Care (1997)								
Germany	The Embryo Protection Act (1990)				The Embryo Protection Act (1990)				
Greece	The law on Medically Assisted Human Reproduction (3089/2002)	General Council for Health Statement (1998)							
Iceland	Act on Artificial Fertilization (55/1996)				Act on Artificial Fertilization (55/1996)				
India		Ethical Policy Document on the Human Genome,						Ethical Policy Document on the Human Genome,	

		Genetic Research and Services, Council of Medical Research (2000)						Genetic Research and Services (2000)	
Israel			Prohibition of Genetic Intervention Law (1999)						
Italy			Ordinance 1997	Law on Assisted Reproduction					
Japan	The Law Concerning Regulation relating to Human Cloning Techniques and other Similar Techniques (2000)					Guidelines in Relation to Handling of Specified Embryos (2001)			Guidelines in Relation to Handling of Specified Embryos (2001) (Currently under revision)
Korea (Republic of)	Bioethics Law (2003)						Bioethics Law (2003)		
Latvia	The Law on Sexual and Reproductive Health (2002)								
Mexico	*The General Health Law (1997)								
Netherlands	The Embryo Act (2002)						The Embryo Act (2002)		
New Zealand	The Medicines (Restricted Biotechnical Procedures)			The Human Assisted Reproductive Technology					The Human Assisted Reproductive Technology

* This legislation implicitly prohibits reproductive cloning of human beings

	Amendment Act (2002)			Bill (1996), The Assisted Human Reproduction Bill (1998)					Bill (1996)
Norway	The Law No. 56 on the Medical Use of Biotechnology (1994)				The Law No. 56 on the Medical Use of Biotechnology (1994)				A Bill of 2002
Peru	The General Health Law (1997), Criminal Code				The General Health Law (1997)				
Philippines				An act prohibiting the Cloning of Humans and Providing Penalties for Violations Thereof (2003)					
Portugal		National Council of Ethics for the Life Sciences Opinion (1997)							
Russian Federation			The Law on the Temporary Prohibition of Human Cloning (2002)						
Singapore		BAC recommendation (2002)						BAC recommendation (2002)	
Slovakia	Health Care Act no. 277/1994, Slovak Penal Code				Health Care Act no. 277/1994				

Spain	Law 35-1988 concerning medically assisted human reproduction				Law 35-1988 concerning medically assisted human reproduction			
South Africa	*The Law on Human Tissue (1983)			National Health Bill (1998)	The Law on Human Tissue (1983)			
Sweden	*The Law concerning measures for the purposes of research or treatment in connection with fertilized human oocytes (1991)				The Law concerning measures for the purposes of research or treatment in connection with fertilized human oocytes (1991)		Swedish Research Council (2001)	
Switzerland	Federal Constitution, Federal Law on Medically Assisted Procreation (1998)				Federal Constitution, Federal Law on Medically Assisted Procreation (1998)			
Thailand		Regulations on Human Cloning No. 21/2544 (2002), Medical Council: Stem Cell Guideline, (2003) Bioethics and Advanced Biomedical Research Project						

* This legislation implicitly prohibits reproductive cloning of human beings

Trinidad and Tobago				Bill No.4 Respecting Human Reproductive Technologies and Commercial Transactions Relating to Human Reproduction (1999)					Bill No.4 Respecting Human Reproductive Technologies and Commercial Transactions Relating to Human Reproduction (1999)
United Kingdom	The Human Fertilisation and Embryology Act (1990) Human Reproductive Cloning Act (2001)							The Human Fertilisation and Embryology Act (1990)	
United States of America				Bill H.R. 534 (2003)					Bill H.R. 534 (2003)
Uruguay				Draft Law on Human Assisted Reproduction					Draft Law on Human Assisted Reproduction
Viet Nam	Decree (2003)								