

NATIONAL LEGISLATION CONCERNING HUMAN CLONING AND GERMLINE MANIPULATION

ASIA

CHINA

- § “Guidelines on Assisted Reproductive Technologies for Human Beings,” Ministry of Public Health (August 2003).
<http://www.biol.tsukuba.ac.jp/~macer/EJ141/ej141d.htm>

Par. 3.7, 3.15: “The performance of cytoplasm transfer and germinal vesicle transfer for infertility treatment is forbidden and the (reproductive) cloning of human beings is prohibited.” (*unofficial translation*)

Human reproductive cloning is prohibited.

- § “Ethical Principles on Assisted Reproductive Technologies for Human Beings and Human Sperm Bank,” Ministry of Health (August 2003).
<http://www.biol.tsukuba.ac.jp/~macer/EJ141/ej141d.htm>

Par. 1.3.g “cytoplasm transfer and germinal vesicle transfer should not be allowed for infertility treatment before the problem of safety is resolved.” (*unofficial translation*)

Under the guidelines research for therapeutic purposes is allowed.

- § “Ethical Guidelines on Human Embryonic Stem Cells,” Chinese Ministry of Science and Technology and Ministry of Health (January 2004).
<http://www.philosophyol.com/academy/ArticleShow.asp?ArticleID=23&ArticlePage=4>
<http://www.biol.tsukuba.ac.jp/~macer/EJ141/ej141d.htm>

Article 4: “Any research for human reproductive cloning shall be prohibited.”

Article 6: “The conduct of human embryonic stem cell research must comply with the following norms: (1) when a blastula is obtained by IVF, somatic cell nucleus transfer technique, monosexual reproduction technique or genetic modification, the culture period in vitro cannot be more than 14 days since fertilization or nucleus transfer; (2) the implantation of the human blastula which has been used for research into human or other animal's reproductive system is prohibited; (3) the hybrid between human germ cells and germ cells of other species is prohibited.”

- § “The Human Reproductive Technology Ordinance, An Ordinance No. 47”. The Government of the Hong Kong Special Administrative Region (Gazette, Legal Supplement No. 1 to No. 26, Vol. 4, 30 June 2000, pp. A1691-A1777) (Amended 2002)
<http://www.hklli.org.hk/hk/legis/ord/561/>

Section 15: “Prohibitions in connection with embryos, against sex selection and against the provision of reproductive technology procedures to unmarried persons (not yet in operation)

(1) No person shall-

- (e) replace the nucleus of a cell of an embryo with a nucleus taken from any other cell; or
- (f) clone any embryo.”

INDIA

- § “Consultative Document on Ethical Guidelines for Biomedical Research on Human Subjects,” Indian Council of Medical Research (ICMR) (2000).
<http://icmr.nic.in/ethical.pdf>

The section dealing with 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.”

- § “Statement of Specific Principles on Human Genetics Research,” ICMR (20 July 2000).
<http://icmr.nic.in/ethical.pdf>

“III. Therapeutic Trials Including Gene Therapy

ii) Germ Line Therapy is prohibited under the present state of knowledge in these areas.

...

iv) Eugenic Genetic Engineering for selection against personality, character, formation of body organs, fertility, intelligence and physical, mental and emotional characteristics is prohibited.”

“VII. Assisted Reproductive Techniques

Cloning (through nuclear transplantation or embryo splitting): The possibility of human cloning cannot be rejected since sheep and mice have already been cloned. However, since its safety, success, utility and ethical acceptability is not yet established, research on cloning with intent to produce an identical human being, as of today, is prohibited.”

- § “Ethical Policies on the Human Genome, Genetic Research and Services,”
Department of Biotechnology, Ministry of Science and Technology, Government
of India (June 2001).
<http://dbtindia.nic.in/publication/publicmain.html>

“Policies:

Gene Therapy and Human Cloning.-

(2) Considering the present state of knowledge, germline therapy in humans shall
be proscribed. However, research on embryonic stem cell biology may be
undertaken with adequate safety measures.

(3) As a principle, human cloning shall not be permitted.”

JAPAN

- § “Law concerning Regulation Relating to Human Cloning Techniques and Other
Similar Techniques,” (November 2000, in effect since June 2001).
http://www.mext.go.jp/a_menu/shinkou/seimei/eclone.pdf

Article 1:

“(Purpose of the Law)

The cloning techniques and other similar techniques included in
techniques for manipulating embryos or germ cells of a human or an animal
could, depending on the way they are applied, artificially create an
individual with the same genetic structure as a certain individual
(hereinafter referred to as “human clone individual”) or an individual which
cannot be clearly classified as a human or an animal (hereinafter referred to
as “amphimictic individual”), or other similar individuals. This could have
a severe influence on preservation of human dignity, safety for human life
and body, and maintenance of social order. Based upon these understandings,
the purpose of this law is to prevent and restrain creation of a human clone
individual and an amphimictic individual, and to regulate artificial creation
of individuals similar to such individuals set forth herein, by means of
prohibiting transfer of embryos produced by the cloning techniques or the
Specific Fusion/Aggregation Techniques into a human or an animal uterus,
by means of regulating production, assignment and import of such embryos,
and by means of taking other necessary measures to secure appropriate
handling of such embryos.”

Article 3:

“(Prohibited Acts)

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.”

- § “Guidelines to the ‘Law concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques,’” Minister of Education and Science (4 December 2001).
http://www.mext.go.jp/a_menu/shinkou/seimei/2001/hai3/17_shishin.pdf (in Japanese)

Regulates the production of cloned embryos and embryo research.

- § Commentaries to the Guidelines mentioned above by the Ministry of Education and Science
http://www.mext.go.jp/a_menu/shinkou/seimei/2001/hai3/20_shishin.pdf (in Japanese)

- § “The Guidelines for Handling of a Specified Embryo,” Ministry of Education, Culture, Sports, Science and Technology (1 January 2001).
http://www.mext.go.jp/a_menu/shinkou/seimei/2001/hai3/31_shishin_e.pdf

Section I:

“Requirements for Production of a Specified Embryo

Article 1(Requirements for Production of a Specified Embryo)

Production of a Specified Embryo shall be allowed only when the following requirements are satisfied:

1. Scientific knowledge, which cannot be acquired from research with only animal embryos or cells or other research without a Specified Embryo, is acquired from production of such a Specified Embryo; and
2. A person who is going to produce a Specified Embryo (hereinafter referred to as a "Producer") has technical ability sufficient to study with such a Specified Embryo.”

“Article 9 (Prohibition of Transfer of a Specified Embryo into the Uterus)
Specified Embryos, except for ones prescribed in Article 3 of 'the Law Concerning Regulation Relating Human Cloning Techniques and Other Similar Techniques (Law No. 146, 2000)' (hereinafter referred to as "the Law"), shall not be transferred into the uterus of a human or an animal for the present.”

REPUBLIC OF SOUTH KOREA

- § “Life Ethics Law” (29 January 2004).

The Life Ethics Law regulates embryonic stem cell research. According to the law only supernumerary embryos produced for infertility treatments can be used for research, therefore the creation of embryos for purposes other than infertility treatment is prohibited. However, the government will approve limited research

on somatic cell nuclear transfer based on the guidelines drawn up by the National Ethics Committees.

Human reproductive cloning is prohibited and subject to criminal sanctions for up to ten years in prison.

(“Biological Ethics Bill Passed by National Assembly,” Korean Ministry of Health and Welfare, Press Release (14 January 2004)).

- § “Guidelines on the Safety of Biotechnology Research,” Ministry of Health and Welfare (December 2000)

The guidelines prohibit the manipulation of the human germline, the creation of IVF embryos solely for research purposes and the cloning human beings.

(South Korea: Human Embryo Research, Young-Rhan Um, Special Section: Bioethics Now: International Voices 2003, Cambridge Quarterly of Health Care Ethics (12, pp. 268-278, 2003)).

SINGAPORE

- § “Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning” Report of the Bioethics Advisory Committee of Singapore (BAC) (21 June 2002). On 18 July 2002, the government approved the BAC recommendations.

<http://www.bioethics-singapore.org/resources/reports1.html>

Recommendation 5: “The creation of human embryos specifically for research 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.”

Recommendation 7: “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 or by SCNT 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.”

- § “Human Cloning and Other Prohibited Practices Bill” (May 2004)
http://www.moh.gov.sg/cmaweb/_econsult/112/hc_bill_2004-8.pdf

Part III:
“PROHIBITED PRACTICES

Division 1. Human cloning

Prohibition against placing human embryo clone in body of human or animal

5. No person shall place any human embryo clone in the body of a human or the body of an animal.

Prohibition against importing and exporting human embryo clone

6. No person shall knowingly:

- (a) import any human embryo clone into Singapore; or
- (b) export any human embryo clone out of Singapore.

No defence that human embryo clone could not survive

7. It shall not be a defence to an offence under section 5 or 6 that the human embryo clone did not survive or could not have survived.

Prohibition against developing human embryo created other than by fertilisation of human egg by human sperm

8. No person shall develop any human embryo, that is created by a process other than the fertilisation of a human egg by human sperm, for a period of more than 14 days, excluding any period when the development is suspended.

Prohibition against placing prohibited embryo in body of woman

12. No person shall place any embryo in the body of a woman knowing that, or reckless as to whether, the embryo is a prohibited embryo.”

THAILAND

§ “Regulations on Human Cloning No. 21/2544,” Medical Council of Thailand (June 2002).

The regulations ban human reproductive cloning.

(“National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

VIETNAM

§ “Government Decree banning human cloning and surrogacy” (May 2003).

(“National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

AFRICA

SOUTH AFRICA

§ “Law on Human Tissue” (1983) (s.39A inserted by s.26 of Act No. 51 of 1989)
http://www.iucnrosa.org.zw/elisa/Environmental%20Law/south_africa/human_tissue_act.html

39A: “Genetic manipulation of gametes or zygotes is not permitted. 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.”

The Law on Human Tissue implicitly prohibits the cloning of human cells.

§ “Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research,” The Medical Research Council of South Africa (1 April 2002)
http://www.sahealthinfo.org/ethics/eth_icsbook2.pdf

“3.7 Summary of Recommendations

3.7.1.2 Germ-line gene therapy

Gene therapy should be directed to alleviating disease in individual patients, although wider applications may soon call for attention. In the present state of knowledge, any attempt by gene modification to change human traits not associated with disease would not be acceptable.

It is recommended that the necessary research should continue. There is, at present, insufficient knowledge to evaluate the risks, to future generations, of gene modification of the germ line. It is therefore recommended that gene modification of the human germ line should not yet be attempted.

...

3.7.3 Cloning

3.7.3.1 Therapeutic cloning

It is recommended that, at present, the use and derivation of human stem cells should be limited to two sources: cadaveric fetal tissue and 'surplus' embryos remaining after infertility treatments.

It is also recommended that the following principles drawn from the recommendations of the US National Bioethics Advisory Committee should regulate the donation of human embryos for stem cell research.

1. Prospective donors should be given timely, relevant and appropriate information to make informed and voluntary decisions regarding the donation of the embryos.
2. Embryos and cadaveric fetal tissue should under no circumstances be bought or sold.

With regard to the growth of entire organs, it is recommended that this technique should be more thoroughly investigated in animal systems before experimentation with human tissue is permitted.

3.7.3.2 Reproductive cloning

It is recommended that in the use of nuclear transfer the reproductive needs of an individual should not over-ride the best interests of the child produced.

The risk attached to the use of the technique on humans carries the possibility of hormonal manipulation in the egg donor, multiple miscarriages in the birth mother, and severe developmental abnormalities in any resulting child. The potential harms outweigh the potential benefits, and until studies in animal systems reverse this circumstance, we recommend that the use of human nuclear transfer cloning to create a new life should be prohibited.

Critics have raised questions about the appropriate use of scarce resources. This is particularly important in South Africa where public policy has determined that the extension of primary health care to all South Africans must be the nation's first priority in the field of medical care. Is research into, and the practice of cloning, responsible use of limited State resources? The answer must be negative.”

§ “National Health Bill B32-2003” (20 June 2003).
http://www.parliament.gov.za/pls/portal/web_app.utl_output_doc?p_table=draft_bills&p_doc_col=draft_bill&p_mime_col=mime_type&p_id=588648

“1. Definitions ... ‘cloning’ means the creation of identical human organisms from living or dead individuals by manipulation of genetic material, including—
(a) removal of nuclear material from an oocyte or a female gamete, embryo or embryo cells and replacing it with nuclear material from a zygote or somatic cell at any stage from foetal to adult development; or
(b) embryo splitting or blastomere separation of any of the cells which originate from a fertilised ovum.”

“Prohibition of reproductive cloning of human beings

62. (1) A person may not—

- (a) manipulate any genetic material, including genetic material of human

gametes, zygotes or embryos; or
 (b) engage in any activity, including nuclear transfer or embryo splitting, for the purpose of the reproductive cloning of a human being.
 (2) The Minister may, under such conditions as may be prescribed, permit therapeutic cloning utilizing adult or umbilical cord stem cells.
 (3) No person may import or export human zygotes or embryos without the prior written approval of the Minister.
 (4) The Minister may permit research on stem cells and zygotes which are not more than 14 days old on a written application and if—
 (a) the applicant undertakes to document the research for record purposes; and
 (b) prior consent is obtained from the donor of such stem cells or zygotes.
 (5) Any person who contravenes a provision of this section or who fails to comply therewith is guilty of an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.”

TUNISIA

§ “Opinion No. 3,” National Medical Ethics Committee (1997).

At the request of the Minister of Health, the National Medical Ethics Committee analyzed the issue of human cloning. 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, leaving the door open to all forms of abuse.

(“National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

NORTH AMERICA

CANADA

§ “An Act Respecting Assisted Human Reproduction and Related Research (Bill C-6),” Canada/Government, Ottawa (29 March 2004).
http://www.hc-sc.gc.ca/english/pdf/protection/ahr/C-6_4_RA.pdf

“Interpretation and Application - Definitions

3. The following definitions apply in this Act.

“human clone” means an embryo that, as a result of the manipulation of human Reproductive material or an *in vitro* embryo, contains a diploid set of

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chromosomes obtained from a single—living or deceased—human being, foetus or embryo.”

“Prohibited Activities - Prohibited procedures

5. (1) 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;

(f) alter the genome of a cell of a human being or *in vitro* embryo such that the alteration.”

CENTRAL AMERICA

COSTA RICA

§ “Decree No. 24029-S: A Regulation on Assisted Reproduction” (3 February 1995).

<http://www.netsalud.sa.cr/ms/decretos/dec5.htm> (in Spanish)

Article 11: “Any manipulation or alteration of an embryo’s genetic code is prohibited, as is any kind of experimentation with embryos.” (*Author’s translation*)

PANAMA

§ “Law No. 3 Human Cloning Prohibition” (15 January 2004).

http://www.asamblea.gob.pa/legispan/leyes/2004_LEYES/2004_003.pdf (in Spanish)

Article 1: “Is forbidden in all forms the promotion, financing and/or donating, using public funds or private investments, of experiments, research and developments of all forms of human cloning, meaning the creation of an embryo that is the genetic replica of a human being.” (*Author’s translation*)

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ARGENTINA

§ “Decree No. 200/97: A Prohibition on Human Cloning Research” (7 March 1997).
<http://infoleg.mecon.gov.ar/txtnorma/42213.htm> (in Spanish)

Article 1: “experiments concerning cloning of human cells in order to generate human beings are hereby prohibited.” (*Author’s translation*)

At the regional level three provinces have enacted laws prohibiting cloning experiments involving human beings and human reproductive cloning procedures:

§ Law No. 712 on Genetic Heritage Safeguards (regional), Buenos Aires, (25 September 2001). <http://www.cuadernos.bioetica.org/dec200.htm> (in Spanish)

§ Law No. 6581 Province of Mendoza (1998).

§ Law No. 9072 Province of Cordoba (2003).

BRAZIL

§ “Law No. 8974 on genetically modified organisms” (1995)
http://www.mct.gov.br/legis/leis/8974_95.htm (in Portuguese)
<http://www.camara.gov.br/internet/agencia/materias.asp?pk=45234> (in Portuguese)

Article 8 of the law prohibits genetic manipulation of the human germline as well as intervention on human genetic material *in vivo*, with the exception of the treatment of genetic defects which respect ethical principles, such as autonomy and beneficence, and are receive approval from the National Technical Committee on Biosafety - CTNBio.

This article also prohibits the creation, banking and manipulation of human embryos destined to be used as biological material.

Article 13 establishes criminal sanctions (imprisonment for up to twenty years) for violations of the prohibitions contained in Article 8.

After a thorough analysis of Law No. 8974 of 5 January 1995 on the Use of Techniques of Genetic Engineering, the Brazilian Biosafety Technical Commission of the Ministry for Science and Technology concluded that the present legislation can be applied to ban human cloning.

COLUMBIA

§ Criminal Code (24 July 2000).
<http://www.derechos.org/nizkor/colombia/doc/penal.html> (in Spanish)

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The criminal code prohibits “the fertilization of a human ovum with intent other than procreation” and “genetic manipulation for the purpose of the reproductive cloning of a human being,” although it allows “the fertilization of human ova for research and diagnostic purposes if they have a therapeutic goal.” (*Author’s translation*)

PERU

§ “Law No. 26842, General Health Law” (9 July 1997).

Search: www.congreso.gob.pe/

Art. 7: “the fertilization of a human ovum with intent other than procreation is prohibited, as is human cloning.” (*Author’s translation*)

§ “Law No. 27636, Criminal Code: Genetic Manipulation” (16 January 2002).

Genetic manipulation for the purpose of cloning a human being is prohibited. Violating this prohibition results in imprisonment.

EUROPE

COUNCIL OF EUROPE

§ “Additional Protocol (Explanatory Report) to the Convention on Human Rights and Biomedicine” (12 January 1998).

<http://conventions.coe.int/Treaty/en/Treaties/Html/168.htm>

Article 1: “Any intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited. For the purpose of this article, the term human being ‘genetically identical’ to another human beings means a human being sharing with another the same nuclear gene set.”

§ “Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine - Convention on Human Rights and Biomedicine” (Oviedo, 4 April 1997).

<http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>

Article 13: “Interventions on the human genome

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.”

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AUSTRIA

§ “Federal Law (Serial 275) Regulating Medically Assisted Procreation (The Reproductive Medicine Law), and Amending the General Civil Code” (1992).

§ The Marriage Law and the Rules of Jurisdiction. (1993) Search:
<http://www.bmwf.gv.at/> (in German)

The law does not explicitly prohibit the cloning of human beings, but it limits research on human embryos (defined as “developable cells”). Its central principle is that reproductive medicine is acceptable only within a stable heterosexual relationship for the purpose of reproduction.

Article 9 states that fertilized human oocytes and cells derived therefrom may not be used for purposes other than medically assisted reproduction, and any intervention into the germline is strictly prohibited. Any violation or attempt at violation is subject to administrative or criminal prosecution.

(“National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

BELGIUM

§ “Law concerning research on embryos in vitro” (11 May 2003).
Search:
http://www.senat.be/www/webdriver?MIval=index_senate&M=1&LANG=fr

Art. 2: “For the application of the present law, the following definitions apply:
7. Reproductive human cloning – the production of one or more humans whose genes are identical to the person from whom the cloning took place.”

Art. 4:
“1. The creation of *in vitro* embryos for research purposes is forbidden, unless the objective of the research cannot be achieved by research on excess embryos and in as much as the conditions of the present law are met.”

Art. 5: “It is forbidden:
4. to effect research or treatments with a eugenic purpose, in other words focused on the selection or amplification of non pathological genetic characteristics of the human species.”

Art. 6: “Human reproductive cloning is forbidden.” (*Author’s translation*)

DENMARK

- § “Act No. 460 on Medically Assisted Procreation in connection with medical treatment, diagnosis and research” (10 June 1997, amended by Act No. 427, June 2003)

The Act forbids research on human reproductive cloning and somatic cell nuclear transfer (therapeutic cloning).

(“National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

- § “Act No. 503 on a Scientific, Ethical Committee System and the Handling of Biomedical Research Projects” (1992).

Section 15: “The following experiments shall be prohibited:

1. experiments whose purpose is to enable the production of genetically identical human beings;
2. experiments whose purpose is to enable the production of human beings by the fusion of genetically different embryos or parts of embryos prior to their implantation in the uterus;
3. experiments whose purpose is to enable the production of living human beings who are hybrids with a genetic constitution including components from other species; and
4. experiments whose purpose is to enable the development of human beings in the uterus of another species.”

(Karnovs Lovsamling 2 (1995) p. 2819. Translation from: International Digest of Health Legislation Vol. 43, No. 4 (1992) pp. 758-760)

ESTONIA

- § Penal Code (Passed 6 June 2001, entered into force 1 September 2002, (consolidated text Jan 2004)
http://www.legaltext.ee/en/andmebaas/ava.asp?tyyp=SITE_ALL&ptyyp=I&m=000&query=embryo&nups.x=18&nups.y=11

“Illegal Treatment of Embryo or Foetus

§ 130. Prohibited acts with embryo

Human cloning or creating a human hybrid or human chimera is punishable by a pecuniary punishment or up to 3 years’ imprisonment.

§ 131. Abuse of human embryo or foetus

A person who creates a human embryo or foetus *in vitro* without the intention to transfer the embryo or foetus to a woman, or outside an institution duly authorised by law or without the corresponding lawful right, or preserves a human embryo or foetus *in vitro* in an unfrozen form for longer than the term provided by law or performs unauthorised transactions with an embryo or foetus, shall be punished by a pecuniary punishment.”

- § Patents Act (16 March 1994, amended by Act RT I 2003, 18, 106; 29 January 2003)
http://www.legaltext.ee/en/andmebaas/ava.asp?tyyp=SITE_ALL&ptyyp=I&m=000&query=embryo&nups.x=18&nups.y=11

“Chapter II

Patent Protection and Patentability

(2) The following biotechnological inventions shall not be protected by a patent:

- 1) processes for cloning human beings;
- 2) processes for modifying the germ line genetic identity of human beings;
- 3) uses of human embryos for commercial purposes, including processes prohibited by the Artificial Insemination and Embryo Protection Act.”

FINLAND

- § “The Act on Medical Research, No. 488/1999” (1999).
<http://www.finlex.fi/pdf/saadkaan/E9990488.PDF>

Section 11: *“Conditions governing research involving embryos*

Research on embryos outside a woman’s body may be carried out only by agencies that have been granted the appropriate licence by the National Authority for Medicolegal Affairs. The conditions for the granting of the licence shall be laid down by Decree.

Medical research shall be permitted on embryos only if no more than 14 days have passed from their formation. The time during which an embryo is kept frozen shall not count for the purposes of calculating this time limit.”

Section 12: *“Consent for research on embryos*

Research on embryos outside a woman’s body may not be undertaken without the written consent of the persons who donated the gametes. The donors shall be provided with the information referred to in section 6(2). Consent may be withdrawn on the same terms as set out in section 6(3).

Embryos produced from donated gametes may not be used for research once the withdrawal of consent has been received.

Research on an embryo inside a woman’s body may not be undertaken without her written consent.”

Section 13: *“Restrictions on research on embryos*

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The production of embryos exclusively for the purpose of research shall be forbidden. Embryos that have been used for research may not be implanted in a human body or be kept alive for longer than 14 days from their formation, not including any time during which they have been kept frozen.

Research may use embryos that have been stored for up to 15 years, after which the embryos must be destroyed.”

Section 15: “*Prohibited research*

Research on embryos and gametes for the purpose of developing procedures for modifying hereditary properties shall be prohibited, unless the research is for the purpose of curing or preventing a serious hereditary disease.”

Section 25: “*Unlawful research on embryos and gametes*

Any person who conducts research on embryos without the licence referred to in section 11 or in contravention of the restrictions laid down in sections 11 and 13, or who in contravention of the prohibition in section 15 conducts research on embryos or gametes, shall be fined or imprisoned for a period not exceeding a year for *unlawful research on embryos and gametes*.”

Section 26: “*Unlawful intervention on the genome*

Any person who conducts research with the aim of:

- (1) cloning human beings;
- (2) creating a human being by combining embryos;
- (3) creating a human being by combining human gametes and genes from animals, shall be fined or imprisoned for a period not exceeding two years for *unlawful intervention on the genome*.”

§ “Medical Research Decree, No. 986/1999” (1999).
<http://www.finlex.fi/pdf/saadkaan/E9990986.PDF>

Section 4: “*Conditions governing institutions that are carrying out research involving embryos*

The condition for granting a licence referred to in section 11 of the Medical Research Act is that the institution has appropriate research facilities and equipment, as well as the staff needed for the activity.

When an institution applies for a licence referred to in paragraph 1 from the National Authority for Medicolegal Affairs, the institution shall append to the application information about:

- 1) the content and extent of the research;
- 2) the facilities used for the research;
- 3) devices and equipment used for the research;
- 4) staff engaged in the research;
- 5) quality assurance of the research; and
- 6) the ethics committee assessing the research.

If the applicant is an institution referred to in the Private Health Care Act (152/1990), to the application shall be attached, in addition, information about the licence granted to the institution.

The National Authority for Medicolegal Affairs will issue, if necessary, further instructions for the application procedure.”

FRANCE

- § “Bioethics Law” (8 July 2004, amended Law No. 94-653 of July 29 1994, on Respect for the Human Body and Law No. 94-654 of July 29 1994, on the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis.)

Part I:

<http://www.senat.fr/pl/106-1ere-partie-0304.pdf> (in French)

Part II:

<http://www.senat.fr/pl/106-2eme-partie-0304.pdf> (in French)

The bioethics legislation and its amendments specifically prohibit human cloning for reproductive and therapeutic purposes, germline gene therapy and the creation of embryos purely for research purposes.

Human reproductive cloning is considered a “crime against the human race” and has been criminalized with jail sentences of up to 20 years and the imposition of fines; research or therapeutic cloning is punishable with up to 7 years in prison and fines.

GEORGIA

- § “Law on the rights of the patients” (5 May 2000).
<http://www3.who.int/idhl-rils/results.cfm?language=english&type=ByCountry&strRefCode=Geo&strTopicCode=XIA>

Chapter VI: “Rights in the field of genetic counseling and gene therapy
Section 33 Interventions to modify the genome may only be carried out for diagnostic, therapeutic, or preventive purposes; they may not be aimed at modifying the genome of the patient's descendants.”

- § “Law on Health Care” (10 December 1997)
<http://www3.who.int/idhl-rils/results.cfm?language=english&type=ByCountry&strRefCode=Geo&strTopicCode=IA>

Section 142:

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<http://www.thehumanfuture.org>

“(1) Human cloning through the use of genetic engineering shall be prohibited.
(2) The State shall control research in the field of genetic engineering in accordance with the law.”

GERMANY

§ “Federal Embryo Protection Law” (1990) (Bundesgesetzblatt, Part 1, December 19, 1990, pp. 2746-2748)
<http://www.bmgesundheit.de/rechts/genfpm/embryo/embryo.htm> (in German)
Search http://www.bundestag.de/htdocs_e/index.html

“5. (1) Any person who artificially alters the genetic information of a human germline cell shall be punished by up to five years' imprisonment or by a fine.
(2) The same penalty shall be imposed on any person who uses a human germ cell with artificially modified genetic information for fertilization.

Clones

6. (1) Any person who artificially causes a human embryo to develop with the same genetic information as another embryo, fetus, living person, or deceased person shall be punished by up to five years' imprisonment or by a fine.
(2) The same penalty shall be imposed on a person who transfers an embryo as specified in subsection 1 into a woman.
(3) Attempts shall be punishable.

Creation of chimeras and hybrids

7. (1) A penalty of up to five years' imprisonment or a fine shall be imposed on any person who attempts:
1. to unite in one syncytium embryos with different genetic information, involving the use of at least one human embryo;
2. to combine a human embryo with a cell that contains different genetic information from the embryo cells, and which is capable of subsequent differentiation; or
3. by fertilization of a human egg cell with the sperm of an animal or by fertilization of an animal's egg cell with the sperm of a man, to produce an embryo capable of differentiation.
(2) The same penalty shall be imposed on any person who attempts:
1. to transfer an embryo produced by a procedure as specified in subsection 1 into:
(a) a woman; or
(b) an animal; or
2. to transfer a human embryo into an animal.”

Definitions

8. (1) For the purpose of this Law, the term "embryo" means the human egg cell, fertilized and capable of development, from the time of fusion of the nuclei, as well as each totipotent cell removed from an embryo that is capable, in the

presence of other necessary conditions, of dividing and developing into an individual”

GREECE

§ “Law No. 3089 on Medically Assisted Reproduction” (2002).

Prohibits *inter alia* reproductive cloning.

(“National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

HUNGARY

§ “Law No. 154 on public health” (15 December 1997).

<http://www3.who.int/idhl-rils/results.cfm?language=english&type=ByCountry&strRefCode=Hung&strTopicCode=IA>

Chapter VIII. Medical research on human subjects (Sections. 157-164). Under Section 162, research and manipulations aimed at or giving rise to changes in the genetic heritage of the human being may only be carried out for preventive, diagnostic, or therapeutic purposes and provided that, subject to the exceptions referred to in subsections 1 and 2 of Section 182, the purpose of such research or manipulation is not to modify the genetic heritage of a person's descendants or to create a new individual.

ICELAND

§ “Artificial Fertilisation Act No. 55” (29 May 1996)

<http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/685>

Art. 11: “Research on embryos

All research, experiments and operations on embryos is prohibited.

Nevertheless, it is permitted to carry out research on embryos:

- a) if it is part of an in vitro fertilisation 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.”

Art. 12: “It is prohibited to:

- a) cultivate or produce embryos solely for research purposes,
- b) cultivate embryos for more than 14 days outside the body or once the primitive streak has appeared,
- c) transplant human embryos into animals, and
- d) perform cloning.”

Art. 14: “Violation of the provisions of this Act or of rules based on it entails fines or imprisonment of up to three months under the terms of this Act.

Participation in such a violation shall entail the same penalties, unless more severe penalties apply under other legislation.”

§ “Regulation No. 568/1997 on Artificial Fertilisation,” Iceland Ministry of Health and Social Security (30 September 1997).

<http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/686>

Article 22: “Any research, experiments and operations on embryos shall be prohibited.

Nevertheless, it is permitted to do research on embryos:

- 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 increase understanding of the causes of innate diseases and miscarriages.

It is prohibited to carry out research pursuant to points c) and d) unless it meets the conditions of Article 1 (8) on scientific research and the approval of the Scientific Ethics Committee or ethics committees has been obtained pursuant to Article 29 of Act No. 74/1997 on the Rights of Patients.”

Article 23: “It is prohibited to:

- a) cultivate or produce embryos solely for research purposes,
- b) cultivate embryos for more than 14 days outside the body or once the primitive streak has appeared,
- c) transplant human embryos into animals and
- d) perform cloning.”

Article 24: “Infringement of these rules is subject to fines or imprisonment of up to three months, cf. Article 14 of Act No. 55/1966 on Artificial Fertilization.

Participation in such an infringement shall be punishable in the same way unless it is subject to a more severe punishment according to other laws.”

§ “Act on the Rights of Patients, No. 74/1997” (1997).

IRELAND

- § Constitution of Ireland
<http://193.178.1.117/upload/publications/297.pdf>

Article 40 (3.3°) “The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right.”

The Constitution is interpreted as an implicit prohibition on human cloning.

ITALY

- § “Assisted Medical Procreation Law” (10 February 2004).
<http://www.parlamento.it/att/giornal/home.htm> (in Italian)
<http://www.parlamento.it/att/giornal/home.htm>
[http://www.senato.it/bgt/ShowDoc.asp?leg=14&id=00090801&tipodoc=Ddlmess
&modo=PRODUZIONE](http://www.senato.it/bgt/ShowDoc.asp?leg=14&id=00090801&tipodoc=Ddlmess&modo=PRODUZIONE)

Article 13 of the law prohibits the prohibition of embryos solely for research purposes or any other purpose not explicitly authorized in the law. It further prohibits the “selection, manipulation or any other procedure directed at altering the genetic patrimony/heritage of the embryo or the gamete. This is to predetermine their genetic characteristics, with the exception of diagnostic and therapeutic purposes contemplated in article 13.2.”

The law also forbids “cloning interventions by means of nuclear transfer or early embryo splitting whether for reproductive or therapeutic purposes.” (*Author’s translation*)

LATVIA

- § “Law on Sexual and Reproductive Health” (July 2002).

The Law on Human Reproductive and Sexual Health regulates human medically assisted reproduction and the protection of the embryo. Article 16 of the law prohibits human cloning, or the use of medical techniques to create a human being genetically identical to another, alive or dead; it also forbids the creation of human embryos for research and therapeutic cloning.

Under the Act research on human embryos may be authorized if the following conditions are met: absence of alternative method, positive assessment of the scientific merit and ethical acceptability by an authorized body, and informed consent of the donors.

There are no regulations directly addressing human embryonic stem cells research and use, but research on embryos *in vitro* is allowed under Regulations of the Ministry of Welfare.

(Report on Human Embryonic Stem Cell Research, Commission of the European Communities. Brussels, April 3 2003.

“National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

LITHUANIA

§ “Law on Ethics of Biomedical Research No. VIII-1679” (11 May, 2000)
<http://www3.lrs.lt/c-bin/eng/preps2?Condition1=148740&Condition2>

Article 3: “Objectives, Subjects and Characteristics of Biomedical Research
2. Human embryos may be subjects only of clinical observations (non-invasion investigations). Other clinical investigations involving human embryos and their creation for purposes of biomedical research shall be prohibited. Human embryos may be subjected to such biomedical research where the medical risks for the embryo are not disproportionate to the potential benefits.
3. Cloning of a human being shall be prohibited.”

THE NETHERLANDS

§ “The Embryos Act” (July 2002).
<http://www.minvws.nl/documents/IBE/wetstekst/eng-embryowettekst.pdf> (in Dutch)

“The Embryo Act, which came into effect on 1 September 2002, sets conditions for and restrictions on the use of embryos and gametes in the Netherlands. It bans the cloning of human beings as well as any experiments combining human and animal cells. Under this Act, a baby's sex may not be predetermined, nor may the genetic code of gametes or embryos be changed. Embryos may not be produced for any purpose other than pregnancy. The Act also bans trade in gametes and embryos.

People who have successfully undergone IVF treatment may donate the gametes or embryos they no longer need to a third party to produce embryonic stem cells

or for scientific research. Out of respect for human life, the Embryo Act bans the production of embryos purely for research purposes.

Certain conditions apply to scientific research. The results it is expected to yield must be of medical importance. If there are alternative methods, they must be used. Finally, all research programmes must be approved by the Central Committee on Research involving Human Subjects (CCMO).”*

(*Ministry of Health, Welfare and Sports, The Embryos Act; 03/03/2003.

http://www.minvws.nl/en/themes/embryo_act/default.asp)

The Embryos Act prohibits human reproductive cloning and strictly regulates research on embryos. Article 11 prohibits the performance of scientific research with embryos created specifically for this purpose. This prohibition shall not apply to scientific research which is reasonably likely to lead to the identification of new insights in the field of fertility, in the field of artificial reproduction techniques, in the field of congenital diseases or in the field of transplant medicine, and which can only be performed by making use of embryos as referred to in the first sentence.

Article 24 prohibits the use of embryos specifically created for scientific research and purposes other than the generation of a pregnancy; performing procedures with gametes or embryos with a view to the birth of genetically identical human individuals.

(“National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

NORWAY

§ “Law No. 100 on the use of biotechnology in human medicine (the Biotechnology Law)” (5 December 2003, amending Law No. 79 of December 13 2002 and repealing Law No. 56 of 5 August 1994)
<http://www.lovdato.no/all/nl-20031205-100.html> (in Norwegian)

“3.1. *Prohibition of research on fertilized eggs, etc.*

Research on fertilized eggs, human embryos, and cell lines cultured from fertilized eggs or human embryos shall be prohibited.”

“3.2. *Prohibition of the production of human embryos by cloning, etc.*

It shall be prohibited:

- (a) to produce human embryos by cloning;
- (b) to carry out research on cell lines cultured from human embryos produced by cloning; and
- (c) to produce embryos by cloning through the introduction of heritable material

from a human being into an egg cell of an animal.
Cloning means techniques for producing heritable identical copies.”

POLAND

§ “Law on Family Planning, Protection of Human Fetuses, and the Conditions under which Pregnancy Termination is Possible” (January 1993).

Prohibits human reproductive cloning.

((1993) 44: 2 *Int. Dig. Hlth. Leg.*, 253.)

PORTUGAL

§ “Opinion No. 21/CNECV/97 on the Ethical Implications of Cloning,” National Council of Ethics for the Life Sciences (1 April 1997).

<http://www.cneqv.gov.pt/NR/rdonlyres/8EA5B11B-914D-4C81-B24F-DFEC00015EB0/0/P021Clonagem.pdf> (in Portuguese)

“2. The cloning of human beings, because of the problems it raises concerning the human dignity, the equilibrium of the species and life in society, is ethically unacceptable and must be prohibited.”

RUSSIAN FEDERATION

§ “Law on the Temporary Prohibition of Human Cloning” (April 2002).

The 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 preliminary deprived of its nucleus” is subject to a temporary 5-year ban.

The law also prohibits import and export of human cloned embryos for the same period. Persons violating the law will be prosecuted in accordance with the federal legislation. However, neither the Criminal nor Administrative Code provides punishment for cloning acts.

(“National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

SLOVAKIA

§ “The Health Care Law” (1994).

Article 46: “Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.”
Research cloning is implicitly prohibited under Article 42.3c) “research without medical indication is not permitted on human embryos and fetuses.”

§ Slovak Penal Code (Amended September 2003)

Article 246a.

“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 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.”

§ The Patent Act No. 435/2001 Coll. (Amended by the Act No. 402/2002 Coll. (11 November 2001).

www.indprop.gov.sk/english/pravo/43501.pdf

Article 6: “Exceptions to patentability

(2) Pursuant to paragraph 1(e) the following, in particular, shall not be considered patentable:

- a) processes for cloning human beings,
- b) processes for modifying the germ line genetic identity of human beings.”

SLOVENIA

§ “The Law on Medically Assisted Reproduction” (2001).

§ Penal Code (2002).

Human cloning for reproductive, research or therapeutic purposes is forbidden as are inheritable genetic modification procedures.

SPAIN

- § Law No. 35/1988 on Assisted Human Reproduction Techniques (22 November 1988, modified by Organic Law No. 10/995 of 23 November 1995 and amended by Law 45/2003)
http://noticias.juridicas.com/base_datos/Admin/l35-1988.html#a11
http://noticias.juridicas.com/base_datos/Admin/l45-2003.html (in Spanish)

The law No.35/1988 establishes in sections §13.3(d) and 15.2(b) that “any therapeutic intervention, investigation or research activity in pre-embryos *in vitro*, pre-embryos, embryos and fetuses *in utero*, will be authorized only if such intervention or activity does not alter its genetic make-up (in so far as it does not contain any anomaly), or if it is not aimed to individual or race selection”.
(*Author’s translation*)

Article 20.B: “The following are very grave infractions:

- k) The creation of identical human beings, by cloning or other procedures for racial selection.
- l) The creation of human beings by cloning in any of its variations, or any other procedure that can initiate identical human beings.
- m) Parthenogenesis, or stimulating the development of an ovum by any method, physical or chemical, without fertilization by sperm, by solely feminine descent.
- n) Sex selection, or genetic manipulation that is not therapeutic, or is therapeutic but not authorized.” (*Author’s translation*)

- § “Law No. 42/88 on the donation and use of human embryos, fetuses and cells, tissues and organs” (28 December 1988).
http://noticias.juridicas.com/base_datos/Admin/l42-1988.html(in Spanish)

- § Penal Code, Law No. 10/95, November 23, 1995
http://noticias.juridicas.com/base_datos/Penal/lo10-1995.html(in Spanish)

The Organic Law introduced in section II of the Penal Code a Title V: Offences relating to genetic engineering, prescribing criminal and civil sanctions for its violation.

The Spanish Penal Code (Article 16 1,2) prohibits bringing about the birth of identical human beings as a result of cloning or other procedures aimed at the selection of humans.

- “1. There will be a penalty of one to five years imprisonment as well as ineligibility for public employment or office for six to ten years for fertilizing a human ovum with any purpose other than human procreation.
- 2. The same penalties apply for the creation of identical human beings by cloning or other procedures directed at racial selection.” (*Author’s translation*)

SWEDEN

§ Law No. 115 an Act concerning measures for the purposes of Research or Treatment in connection with Fertilized Human Oocytes (1993).

The act implicitly prohibits embryo and oocyte cloning. It states that the purpose of experimentation shall not be to develop methods aimed at causing heritable genetic defects. Finally, the act imposes criminal sanctions for the violation of its provisions.

(“National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

§ Act No. 460 on Ethics Review of Research Involving Humans (2003)

This statute and the *in vitro* Fertilization law of 1988 govern embryo research. Any research, which seeks to genetically modify the embryo, is prohibited. The statute implicitly prohibits embryo and oocyte cloning with criminal sanction.

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

<http://www.vr.se/filesserver/index.asp?fil=LCK7HDEK3U6H>

(“Report on Human Embryonic Stem Cell Research,” Commission of the European Communities (Brussels, 3 April 2003); “National Legislation Concerning Human Reproductive and Therapeutic Cloning,” UNESCO Division of the Ethics of Science and Technology (Paris, April 2004).)

SWITZERLAND

§ “Federal Order on the revision of the Federal Constitution” (December 1998).
<http://www3.who.int/idhl-rils/results.cfm?language=english&type=ByCountry&strRefCode=Switz&strTopicCode=IA>

Article 119:

“(1) Human beings shall be protected against abuse with regard to medically assisted procreation and genetic engineering.

(2) The Confederation shall legislate on the use of the human germline and genetic heritage. In doing so, it shall ensure that human dignity, personhood, and the family are protected and that the following principles are respected:

a. any form of cloning and any intervention involving the genetic heritage of human gametes and embryos is prohibited;

...

c. recourse to medically assisted procreation methods may be authorized only in cases where sterility or the danger of the transmission of a serious disease cannot be averted in any other way, and not for the development of certain qualities in the child or for research; the fertilization of human oocytes outside the body of a woman shall be authorized only under the conditions laid down by law; only the number of human oocytes that may be immediately implanted may be developed to the embryo stage outside the body of a woman;

e. there may be no trade involving human germline material or products resulting from embryos.”

§ "Federal Act on Research on Surplus Embryos and Embryonic Stem Cells(Embryonic Research Act),” Swiss Government (8 April 2004).
<http://www.admin.ch/ch/f/ff/2003/7481.pdf> (in French)

Article 3: “Forbidden practices

1. It is forbidden to:

- a. produce an embryo for research purposes (art. 29 para 1 of the law of 18 December 1998 on Medically Assisted Procreation), produce stem cells from such an embryo or use such stem cells;
- b. modify the hereditary patrimony of germ cells (art. 35, para 1, of the law of 18 December 1998 on Medically Assisted Procreation), produce embryonic stem cells from an embryo whose germline was modified, or use such cells;
- c. create a clone, a chimera or a hybrid (art. 36, para 1, of the law of 18 December 1998 on Medically Assisted Procreation), produce embryonic stem cells from a clone, a chimera or a hybrid, or use such cells;
- d. develop a parthenote, produce embryonic stem cells from a parthenote, or use such cells;
- e. import or export an embryo of the kind described in a. or b., a clone, a chimera, a hybrid or a parthenote.” (*Author’s translation*)

Section 5: Penal Provisions

Art. 24: “Offences

Is liable for imprisonment anyone who, intentionally:

1. produced embryonic stem cells from an embryo created for research purposes, from an embryo whose genetic patrimony was modified, or from a clone, a chimera, a hybrid or a parthenote, used such cells or imported or exported such an embryo, clone, chimera, hybrid or parthenote (art. 3, para 1).” (*Author’s translation*)

TURKEY

§ “Regulation on In Vitro Fertilization and Embryo Transfer Centers” (1996)

Prohibits human reproductive cloning.

UNITED KINGDOM

§ “Human Reproductive Cloning Act 2001,” UK Stat. 2001 c23 &1, (in force 4 December 2001).

<http://www.legislation.hmso.gov.uk/acts/acts2001/20010023.htm>

Article 1: “The offence

- (1) A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence.
- (2) A person who is guilty of the offence is liable on conviction on indictment to imprisonment for a term not exceeding 10 years or a fine or both.
- (3) No proceedings for the offence may be instituted-
 - (a) in England and Wales, except with the consent of the Director of Public Prosecutions;
 - (b) in Northern Ireland, except with the consent of the Director of Public Prosecutions for Northern Ireland.”

MIDDLE EAST

ISRAEL

§ “Law 5759-1999 - Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells)” (1999, amended March 2004).

“Purpose of Law

1. The purpose of this Law is to determine a prescribed period of five years during which no kind of genetic intervention shall be performed on human beings in order to examine the moral, legal, social and scientific aspects of such kinds of intervention and the implications of such for human dignity.”

“Definitions

2. In this Law

(...) Human cloning - the creation of a complete human being, chromosomally and genetically absolutely identical to another person or fetus, living or dead;

Reproductive cell – human spermatozoon or ovum.”

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“Genetic intervention prohibited

3. Throughout the period during which this Law is in force, no person shall perform any act of intervention in the cells of any person with one of the following purposes:

(1) Human cloning;

(2) Causing the creation of a person by use of reproductive cells that have undergone a permanent intentional genetic modification (Germ Line Gene Therapy).”

OCEANIA

AUSTRALIA

§ The Research Involving Human Embryos Act No. 145, “An Act to regulate certain activities involving the use of human embryos, and for related purposes.” (2002)

<http://scaleplus.law.gov.au/html/comact/11/6603/pdf/1452002.pdf>

Article 11: “Offence—use of embryo that is not an excess ART embryo.

A person commits an offence if:

(a) the person intentionally uses, outside the body of a woman, a human embryo that is not an excess ART embryo; and

(b) the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre, and the person knows or is reckless as to that fact.

Maximum penalty: Imprisonment for 5 years.”

§ “Prohibition of Human Cloning Act No. 144, “An Act to prohibit Human Cloning and Other unacceptable practices associated with reproductive technology, and for related purposes” (2002)

<http://www.nhmrc.gov.au/embryo/pdf/prohibit.pdf>

<http://scaleplus.law.gov.au/html/comact/11/6603/pdf/1452002.pdf>

“Part 2—Prohibited practices

Division 1—Human cloning

9. Offence—creating a human embryo clone

A person commits an offence if the person intentionally creates a human embryo clone.

Maximum penalty: Imprisonment for 15 years.

10. Offence—placing a human embryo clone in the human body or the body of an animal

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.

Maximum penalty: Imprisonment for 15 years.

11. Offence—importing or exporting a human embryo clone

(1) A person commits an offence if the person intentionally imports a human embryo clone into Australia.

Maximum penalty: Imprisonment for 15 years.

(2) A person commits an offence if the person intentionally exports a human embryo clone from Australia.

Maximum penalty: Imprisonment for 15 years.

12. No defence that human embryo clone could not survive

It is not a defence to an offence under section 9, 10 or 11 that the human embryo clone did not survive or could not have survived.”

“Section 13

Division 2—Other prohibited practices

13. Offence—creating a human embryo other than by fertilisation, or developing such an embryo.

A person commits an offence if the person intentionally creates a human embryo by a process other than the fertilisation of a human egg by human sperm, or intentionally develops a human embryo so created.

Maximum penalty: Imprisonment for 10 years.

14. Offence—creating a human embryo for a purpose other than achieving pregnancy in a woman.

(1) A person commits an offence if the person intentionally creates a human embryo outside the body of a woman, unless the person’s intention in creating the embryo is to attempt to achieve pregnancy in a particular woman.

Maximum penalty: Imprisonment for 10 years.

(2) Despite subsection 13.3(3) of the *Criminal Code*, a defendant does not bear an evidential burden in relation to any matter in subsection (1) of this section.

15. Offence—creating or developing a human embryo containing genetic material provided by more than 2 persons.

A person commits an offence if the person intentionally creates or develops a human embryo containing genetic material provided by more than 2 persons.

Maximum penalty: Imprisonment for 10 years.

17. Offence—using precursor cells from a human embryo or a human fetus to create a human embryo, or developing such an embryo.

A person commits an offence if the person uses precursor cells taken from a human embryo or a human fetus, intending to create a human embryo, or intentionally develops an embryo so created.

Maximum penalty: Imprisonment for 10 years.

18. Offence—heritable alterations to genome

(1) A person commits an offence if:

(a) the person alters the genome of a human cell in such a way that the alteration is heritable by descendants of the human whose cell was altered; and

(b) in altering the genome, the person intended the alteration to be heritable by descendants of the human whose cell was altered.

Maximum penalty: Imprisonment for 10 years.

(2) In this section: *human cell* includes a human embryonal cell, a human fetal cell, human sperm or a human egg.

22. Offence—importing, exporting or placing a prohibited embryo

(1) A person commits an offence if the person intentionally imports an embryo into Australia knowing that, or reckless as to whether, the embryo is a prohibited embryo.

Maximum penalty: Imprisonment for 10 years.

(2) A person commits an offence if the person intentionally exports an embryo from Australia knowing that, or reckless as to whether, the embryo is a prohibited embryo.

Maximum penalty: Imprisonment for 10 years.

(3) A person commits an offence if the person intentionally places an embryo in the body of a woman knowing that, or reckless as to whether, the embryo is a prohibited embryo.

Maximum penalty: Imprisonment for 10 years.

(4) In this section: *prohibited embryo* means:

(a) a human embryo created by a process other than the fertilisation of a human egg by human sperm; or

(b) a human embryo created outside the body of a woman, unless the intention of the person who created the embryo was to attempt to achieve pregnancy in a particular woman; or

(c) a human embryo that contains genetic material provided by more than 2 persons; or

(d) a human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period when development is suspended; or

(e) a human embryo created using precursor cells taken from a human embryo or a human fetus; or

- (f) a human embryo that contains a human cell (within the meaning of section 18) whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered; or
- (g) a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or
- (h) a chimeric embryo or a hybrid embryo.”

NEW ZEALAND

§ “The Medicines (Restricted Biotechnical Procedures) Amendment Act” (2002).
<http://rangi.knowledge-basket.co.nz/gpacts/public/text/2002/an/014.html>

"96A Interpretation

In this Part, unless the context otherwise requires,

biological material means

- (a) the whole or part of any organ, bone, tissue, or cell; or
- (b) blood or body fluids

cloned human organism means an artificially formed zygote or an artificially formed embryo whose genetic structure is a copy (whether identical or not) of another zygote or embryo, or of a foetus, or of a dead or living human being, or of a still-born child.

cloning procedure means the insertion or injection into a human being of a cloned human organism

genetically modified embryo means a zygote or an embryo whose genetic structure has, as a result of artificial processes, been modified

genetically modified gamete means an ovum or a sperm whose genetic structure has, as a result of artificial processes, been modified

germ-cell genetic procedure means the artificial insertion or injection into a human being of

- (a) a genetically modified gamete; or
- (b) a genetically modified embryo; or
- (c) a zygote or an embryo derived from a genetically modified gamete

specified biotechnical procedure means

- (a) any germ-cell genetic procedure; or
- (b) any xenotransplantation; or
- (c) any cloning procedure.”

"96B Restrictions on specified biotechnical procedures

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(1) No person may conduct a specified biotechnical procedure otherwise than in accordance with an authorisation under section 96C or section 96D.

(2) Subsection (1) applies to a person who continues, after the commencement of this section, to conduct a specified biotechnical procedure that was begun before that commencement.

(3) Every person commits an offence and is liable on summary conviction to imprisonment for a term not exceeding 6 months or to a fine not exceeding \$200,000 who contravenes subsection (1).”

"96E Criteria for authorisations

(1) The Minister may grant or recommend an authorisation sought by an application under section 96G only if satisfied that the application relates to the conduct of a specified biotechnical procedure or class of specified biotechnical procedure that meets each of the following criteria:

- (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.

(2) A reference in any of paragraphs (c) to (e) of subsection (1) to issues is a reference to issues raised

- (a) by the conduct of the procedure or class of procedure to which the application relates; and
- (b) by any technology involved in that conduct.

(3) If the Minister is not satisfied that the conduct of the procedure or class of procedure to which the application relates meets any 1 or more of the criteria specified in subsection (1), the Minister

- (a) may direct that advice on the question whether or not the conduct of the procedure or class of procedure meets that criterion (or, as the case may be, those criteria) be obtained from persons who, in the Minister's opinion, are appropriately qualified, or have the appropriate expertise, to advise on the question; and
- (b) after obtaining that advice, may resume his or her consideration of the application on the basis of that advice.”