Act of 5 December 2003 No. 100 relating to the application of biotechnology in human medicine, etc

Cf. earlier Acts of 5 August 1994 No. 56 and 12 June 1987 No. 68

Chapter 1. Purpose and scope

§ 1-1. Purpose of the Act

The purpose of this Act is to ensure that medical applications of biotechnology are utilised for the benefit of everyone in an inclusive society. This shall be done in accordance with the principles of respect for human dignity, human rights and personal integrity and without any discrimination on the basis of genetic constitution, on the basis of the ethical norms that form part of our Western cultural heritage.

§ 1-2. Scope of the Act

This Act applies to the application of biotechnology in human medicine, etc., including medically assisted reproduction, research on embryos and cloning, prenatal diagnosis, postnatal genetic testing, gene therapy, etc.

The Act does not apply to research that has no diagnostic or therapeutic consequences for the participant or where data about an individual person are not linked to that person. The provisions of Chapter 3 are excepted from this provision.

The Act does not apply to autopsies that come within the scope of Chapter 2 of the Act of 9 February 1973 No. 6 relating to transplantation, hospital autopsies and the donation of bodies and the provisions on expert autopsies, see section 228 of the Criminal Procedure Act of 22 May 1981 No. 25.

This Act applies within the realm. The King may by regulations decide that part or all of the Act shall apply in Svalbard and Jan Mayen.

Chapter 2. Medically assisted reproduction

§ 2-1. Definitions

For the purpose of this Act, the following definitions apply:

a) medically assisted reproduction: insemination and in vitro fertilisation,
b) insemination: the introduction of sperm into a woman's body by means other than sexual intercourse,
c) in vitro fertilisation: fertilisation of oocytes (eggs) outside a woman's body.

§ 2-2. Required form of cohabitation

The use of medically assisted reproduction is only permitted if the woman is married or living with a man in a stable relationship resembling marriage.

§ 2-3. Conditions for insemination

Insemination may only take place if the man is infertile or suffers from or is a carrier of a serious hereditary disease.

In special cases, insemination may take place if the woman is a carrier of a serious sex-linked hereditary disease, cf. section 2-13.

§ 2-4. Conditions for in vitro fertilisation

In vitro fertilisation may only take place if the woman or man is infertile or in the case of infertility for which no cause has been identified.

The conditions mentioned in the first paragraph do not apply to such situations as are mentioned in section 2-14.

§ 2-5. Information and consent

The couple shall be given information on the treatment and on the medical and legal consequences it may have. This shall include information on adoption.

Before the treatment is started, the physician who is providing the treatment shall ensure that written consent is obtained from the woman and her husband or partner. If the treatment is repeated, renewed consent shall be obtained.

§ 2-6. Decisions on treatment

The decision to undertake treatment with a view to medically assisted reproduction shall be taken by a physician. The decision shall be based on medical and psychosocial assessment of the couple. Importance shall be attached to the couple's capacity to provide parental care and the best interests of the child.

The physician may obtain any information necessary to make an overall assessment of the couple.

§ 2-7. The child's right to information on the sperm donor

Any person who is born as a result of medically assisted reproduction using donated sperm has a right to information on the sperm donor's identity at the age of 18. A donor register shall assist the child in this matter.

§ 2-8. Donor register

The Ministry shall establish a register for registration of the identity of sperm donors, so that children can exercise their rights pursuant to section 2-7.

§ 2-9. Sperm donors

A sperm donor shall have reached the legal age of majority. The donor must give written consent for the sperm to be used for fertilisation and for his identity to be recorded in the donor register. Consent may be withdrawn until fertilisation has taken place.

A sperm donor shall not be given information on the couple's or the child's identity.

§ 2-10. Selection of sperm donors

The physician who is providing the treatment shall select a suitable sperm donor. The establishment that carries out the medically assisted reproduction procedure shall ensure that the necessary information on the procedure is registered and reported.

§ 2-11. Storage and import of sperm

Only establishments that are specifically authorised to do so may store and import sperm.

Establishments that store donated sperm shall ensure that information on the identity of sperm donors is registered and reported to a donor register.

Sperm shall not be provided for medically assisted reproduction procedures after the death of the donor.

§ 2-12. Regulations

The Ministry may by regulations lay down further provisions on the organisation of sperm banks, the use of donated sperm and the registration and reporting of information on sperm donors.

§ 2-13. Treatment of sperm before fertilisation

Treatment of sperm before fertilisation for the purpose of selecting the sex of the child is only permitted if the woman is a carrier of a serious sex-linked hereditary disease.

§ 2-14. Genetic testing of embryos

Genetic testing of embryos before implantation into the womb, including tests designed to choose the sex of the child (preimplantation genetic diagnosis) may only be carried out in special cases of serious sex-linked hereditary diseases for which no treatment is available.

If special considerations so indicate, the exemptions board mentioned in the third paragraph may grant permission for genetic testing of embryos. Such permission may be granted for serious hereditary diseases for which no treatment is available. The embryos selected must not be genetically modified.

The exemptions board will be appointed by the Ministry. The Ministry will appoint the members and their personal deputies for two years at a time. The board's decisions are not subject to appeal. The Ministry may issue further regulations on the organisation and procedures to be followed by the board.

Before preimplantation genetic diagnosis is carried out, the woman or the couple shall be given genetic counselling and information.

§ 2-15. Use and implantation of embryos

Embryos may only be used for implantation into the woman from whom the oocytes were obtained.

The Ministry may lay down further regulations relating to implantation of embryos in a woman's body after in vitro fertilisation.

§ 2-16. Storage of embryos

Only establishments that are authorised pursuant to section 7-1 to carry out medically assisted reproduction techniques may after authorisation store embryos.

Embryos may not be stored for more than five years, and shall then be destroyed.

§ 2-17. Storage of unfertilised oocytes and ovarian tissue

Only establishments that are authorised pursuant to section 7-1 to carry out medically assisted reproduction techniques may after authorisation store unfertilised oocytes and ovarian tissue.

Unfertilised oocytes and ovarian tissue may only be stored if the conditions relating to medically assisted reproduction set out in this Act have been fulfilled or if a woman is to undergo treatment that may impair her fertility.

Stored unfertilised oocytes and ovarian tissue may only be kept for as long as the interests of the woman from whom they were taken so dictate and it is considered medically justifiable.

Stored unfertilised eggs and ovarian tissue shall be destroyed if the woman dies.

§ 2-18. Prohibition against egg donation and transplantation of gamete-producing organs

The donation of oocytes or parts of oocytes by one woman to another is prohibited.

The transplantation of gamete-producing organs and tissue from one person to another for the purpose of treating infertility is prohibited.

§ 2-19. Authorisation of methods of treatment, etc.

Methods of treatment that come within the scope of section 2-1, the storage and import of sperm, cf. section 2-11, treatment of sperm, cf. section 2-13, and the storage of embryos and unfertilised oocytes and ovarian tissue, cf. sections 2-16 and 2-17, shall be authorised by the Ministry, and may only be used or carried out by establishments that are authorised pursuant to section 7-1.

Before the Ministry decides whether authorisation is to be given, the application shall be submitted to the Norwegian Biotechnology Advisory Board.

Chapter 3. Research on embryos and cloning, etc.

§ 3-1. Prohibition against research on embryos, etc.

It is prohibited to carry out research on fertilised eggs, human embryos and cell lines derived from fertilised eggs or human embryos.

§ 3-2. Prohibition against creating human embryos by cloning, etc.

It is prohibited:

a) to create human embryos by cloning,
b) to carry out research on cell lines derived from human embryos by cloning,
c) to create embryos by cloning by the technique of inserting human genetic material into an animal oocyte.

Cloning is here understood to mean techniques for creating copies that are genetically identical.

§ 3-3. Prohibition against techniques designed to create genetically identical individuals

The use of techniques designed to create genetically identical individuals is prohibited.

Chapter 4. Prenatal diagnosis

§ 4-1. Definition

For the purpose of this Act, prenatal diagnosis means the examination of fetal cells, a fetus or a pregnant women to obtain information about the genetic constitution of the fetus or to detect or exclude a disease or abnormality of the fetus.

Ultrasound examination that forms part of the ordinary health care offered during pregnancy is not considered to be prenatal diagnosis pursuant to the first paragraph, and therefore does not come within the scope of this Act, with the exception of section 4-5.

§ 4-2. Authorisation of prenatal diagnosis

Methods of examination that come within the scope of section 4-1, first paragraph, shall be authorised by the Ministry.

Before the Ministry decides whether authorisation is to be given, the application shall be submitted to the Norwegian Biotechnology Advisory Board.

§ 4-3. Consent

Before prenatal diagnosis, cf. section 4-1, is undertaken, written consent shall be obtained from the person who is to be examined.

§ 4-4. Information and genetic counselling

Before prenatal diagnosis is undertaken, the woman or couple shall be given information on the procedure, including the fact that it is voluntary, the risk associated with carrying out the procedure, what the procedure may reveal and the consequences this may have for the child, the woman, the couple and the family. If there are grounds to suspect a genetic disease, the woman or couple shall also be given genetic counselling.

If the procedure indicates a disease or abnormality of the fetus, the woman or the couple shall be given information and genetic counselling on the disease or abnormality in question, and on their rights and the support that is available.

§ 4-5. Information on the sex of the fetus before the 12th week of pregnancy

Information on the sex of the fetus before the 12th week of pregnancy resulting from prenatal diagnosis or other examination of the fetus shall only be given if the woman is a carrier of a serious sex-linked disease.

§ 4-6. Prenatal paternity testing

Prenatal diagnosis with a view to determining paternity and prenatal paternity testing are prohibited. This does not apply when the pregnancy may be the result of acts such as are described in sections 192 to 199 of the Penal Code.

Chapter 5. Postnatal genetic testing, etc.

§ 5-1. Definitions

For the purpose of this Act, genetic testing means all types of analyses of human genetic material at both nucleic acid and chromosome level, analyses of genetic products and their function, and examination of organs to obtain information on human genetic constitution.

For the purpose of this Act, postnatal genetic testing means:

a) genetic testing to diagnose a disease,
b) presymptomatic genetic testing, predictive genetic testing and testing to determine whether or not a person is a carrier of hereditary disease that will only be expressed in later generations (carrier testing),
c) laboratory genetic testing to determine sex, with the exception of laboratory genetic testing for identification purposes.

§ 5-2. Use of genetic testing

Genetic testing shall only be carried out for medical purposes if it has a diagnostic or therapeutic objective.

§ 5-3. Authorisation of genetic testing

Before genetic testing of the types listed in section 5-1, second paragraph, litra b, is carried out, the Ministry shall give separate authorisation for each disease or predisposition to a disease that is to be tested.

Before the Ministry decides whether authorisation is to be given, the application shall be submitted to the Norwegian Biotechnology Advisory Board.

§ 5-4. Consent

Before genetic testing that comes within the scope of section 5-1, second paragraph, litra b, is carried out, written consent shall be obtained from the person who is to be examined.

Before genetic testing that comes within the scope of section 5-1, second paragraph, litra b, is carried out in the case of a child under the age of 16, written consent shall be obtained from the child's parents or another person who has parental responsibility.

§ 5-5. Genetic counselling

Before, during and after genetic testing that comes within the scope of section 5-1, second paragraph, litra b, the person tested shall be given genetic counselling.

If the person being tested is a child under the age of 16, the child's parents or another person who has parental responsibility shall also be given genetic counselling.

§ 5-6. Genetic screening and pharmacogenetic testing

The King may lay down regulations relating to the authorisation of genetic screening and pharmacogenetic testing. The regulations may make exceptions from the requirements of this Act relating to written consent, genetic counselling, authorisation of establishments and reporting.

§ 5-7. Genetic testing of children

Genetic testing that comes within the scope of section 5-1, second paragraph, litra b, shall not be carried out on children under the age of 16 unless the test can detect a condition for which treatment may prevent or reduce damage to a child's health.

The Ministry may in special cases grant exemptions from the prohibition of the first paragraph.

§ 5-8. Prohibition of the use of genetic information outside the health service

It is prohibited to request, receive, be in possession of or use information on another person obtained through genetic testing that comes within the scope of section 5-1, second paragraph, litra b, or by systematic surveys of hereditary disease within a family.

It is prohibited to ask whether genetic testing or systematic surveys of hereditary disease within a family have been carried out.

The prohibitions of the first and second paragraphs do not apply to establishments that are authorised pursuant to section 7-1 to carry out genetic testing that comes within the scope of section 5-1, second paragraph, or for research purposes. If genetic information is to be used for research purposes, consent must have been obtained from the person from whom the information was obtained.

Health personnel who need the information for diagnostic and therapeutic purposes are excepted from the prohibition of the first and second paragraphs.

§ 5-9. Provision of genetic information to persons other than the patient

For the purpose of this Act, the provision of genetic information to persons other than the patient means the authorised provision by health personnel of information to at-risk relatives of a patient about hereditary disease in the family.

If it has been documented that a patient suffers from or has a predisposition to a hereditary disease, the patient himself may decide whether or not to inform at-risk relatives of his condition.

If the patient himself cannot or does not wish to inform at-risk relatives of this, health personnel may request the patient's consent to inform his relatives, if the conditions of the fifth paragraph are fulfilled and the disease is approved by the Ministry pursuant to the seventh paragraph.

If the patient cannot give his consent to the provision of information to at-risk relatives by health personnel, they may nevertheless provide such information in special cases, if the conditions of the fifth paragraph are fulfilled and the disease is approved by the Ministry pursuant to the seventh paragraph.

Before health personnel contact the relatives, they shall assess whether:

1. the disease in question has serious consequences for the individual's life or health,
2. there is a reasonable probability that the person's relatives are also genetically predisposed to the disease and may develop the disease later in life,
3. there is a documented link between genetic predisposition to the disease and the development of the disease,
4. the genetic tests used to determine whether a person carries a genetic predisposition to the disease are reliable, and
5. there are satisfactory methods of preventing or treating the disease.

If a relative is under the age of 16, only the parents or another person with parental responsibility shall be informed.

The Ministry will determine by regulations or in the individual case the diseases for which provision of genetic information to persons other than the patient is authorised.

Chapter 6. Gene therapy

§ 6-1. Definition

For the purpose of this Act, gene therapy means the transfer of genetic material to human cells for medical purposes or to influence biological functions.

§ 6-2. Conditions for gene therapy

Gene therapy may only be used to treat serious diseases or to prevent the occurrence of such diseases.

Gene therapy on fetuses and embryos and gene therapy that may involve genetic modification of gametes is prohibited.

§ 6-3. Authorisation of gene therapy

Methods of treatment that come within the scope of section 6-2, first paragraph, shall be authorised by the Ministry.

The Ministry may lay down regulations relating to administrative procedures.

Before the Ministry decides whether authorisation is to be given, the application shall be submitted to the Norwegian Biotechnology Advisory Board.

§ 6-4. Consent

Before gene therapy is carried out, written consent shall be obtained from the person who is to be treated. Before gene therapy involving a child under the age of 16 is started, written consent shall be obtained from the child's parents or another person who has parental responsibility.

Chapter 7. General provisions

§ 7-1. Authorisation of establishments

The medical application of biotechnology, etc. that requires authorisation pursuant to sections 2-19, 4-2, 5-3 and 6-3, first paragraph, of this Act may only take place at establishments specifically authorised by the Ministry for the purpose in question. The decision to authorise an establishment shall indicate which forms of medical biotechnology it is permitted to carry out or commission.

The Ministry may lay down further conditions for authorisation in its decision.

§ 7-2. Duty to provide reports

Any establishment that receives authorisation pursuant to section 7-1 shall submit written reports to the Ministry on its activities.

The Ministry will lay down further provisions on the duty to report.

§ 7-3. Norwegian Biotechnology Advisory Board

The King will appoint a board that on request or on its own initiative can give opinions on matters that come within the scope of this Act and other questions relating to biotechnology. The opinions of the board are public unless otherwise required by the statutory duty of confidentiality.

The King may lay down further provisions on the board's activities.

§ 7-4. Regulations

The King may by regulations lay down further provisions to supplement and implement this Act.

§ 7-5. Penal provisions

Any person that wilfully contravenes this Act or provisions laid down pursuant thereto is liable to fines or to a term of imprisonment not exceeding three months. An accomplice is liable to the same penalties.

§ 7-6. Entry into force and transitional provisions

The Act enters into force from the date decided by the King. The King may decide that different provisions of the Act enter into force at different times.

Decisions made pursuant to the Act of 5 August 1994 No. 56 relating to the application of biotechnology in medicine shall continue to apply provided that this is not contrary to this Act or to regulations or individual decisions laid down pursuant to this Act.

§ 7-7. Amendments to other Acts

From the date of entry into force of this Act, the following amendments shall be made to other Acts:

Act of 5 August 1994 No. 56 relating to the application of biotechnology in medicine shall be repealed.