LOVDATA

# Act on human medical use of biotechnology etc. (Biotechnology Act)

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| Date | ACT-2003-12-05-100 |
| Ministry | Ministry of Health and Welfare |
| Last changed | ACT-2021-06-04-53 |
| Entry into force | 01.01.2004, 01.09.2004, 01.01.2005 |
| Changing | ACT-1994-08-05-56 |
| Corrected | 29.03.2022 (punctuation in lists adapted to universal design) |
| Short title | The Biotechnology Act - biotl |

Cf. *previous* laws of 5 August 1994 no. 56, 12 June 1987 no. 68.

## Briefly about the law

The Biotechnology Act is a Norwegian law that contains rules on the human medical use of biotechnology. The purpose of the Act is "to ensure that the medical use of biotechnology is utilised for the good of people in a society where there is room for everyone".

The Act regulates access to the use of biotechnology. This includes assisted fertilization, preimplantation diagnostics, research on fertilized eggs, cloning, fetal diagnostics, use of fetal tissue, genetic examinations of those born and gene therapy.

Read the full article.

**Chapter overview:**



# Chapter 1. Purpose and scope

**Section 1-1.** ***The purpose of the law***

The purpose of this act is to ensure that the medical use of biotechnology is utilized to the best advantage people in a society where there is room for everyone. This must be done in accordance with principles of respect for human dignity, human rights and personal integrity and without discrimination on the basis of heritage sites based on the ethical norms laid down in our Western cultural heritage.

### § 1-2. *Scope of the Act*

The Act applies to human medical use of biotechnology etc. and includes assisted fertilization, research on fertilized eggs and cloning, fetal diagnostics, genetic examinations of newborns and gene therapy etc.

The Act only applies to research if the research participants are to receive health care or individual feedback on the results of genetic examinations in accordance with section 5-1 second paragraph letter b. The provisions in chapter 3 apply to all research.

The Act does not apply to autopsies that fall under the Act of 7 May 2015 No. 26 on Autopsies and the Delivery of Bodies for Teaching and Research or Act of 22 May 1981 No. 25 on the procedure in criminal cases § 228 on expert autopsy.

The law applies in the kingdom. The King can decide in a regulation that the law shall apply in whole or in part to Svalbard and Jan Mayen.

0 Amended by law 7 May 2015 no. 26 (in accordance with 1 January 2016 according to res. 13 Nov 2015 no. 1289), 19 June 2020 no. 78 (in accordance with 1 July 2020).

# Chapter 2. Assisted fertilization

## Section 2-1. *Definitions*

In this Act, the following shall be understood as:

a. assisted fertilization: insemination and fertilization outside the body; b.
insemination: introduction of sperm into the woman in a way other than intercourse; c.
fertilization outside the body: fertilization of eggs outside the woman's body.

**Section 2-2. *Form of cohabitation***

Assisted fertilization can be performed on a woman who is married, cohabiting in a marriage-like relationship or single. Only applicants who live alone are considered single.

0 Amended by law 27 June 2008 no. 53 (corresponding to 1 January 2009 according to res. 27 June 2008 no. 745), 19 June 2020 no. 78 (corresponding to 1 July 2020).

## § 2-3. *Conditions for insemination*

Insemination can take place when the man is unable to conceive, in the case of unexplained infertility or when the man himself has or is a carrier of a serious hereditary disease, when two women are married or cohabiting in a marriage-like relationship or on a single woman.

Insemination can also take place when the man or woman is contagious with a serious and chronic sexually transmitted infection.

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

0 Amended by laws 27 June 2008 no. 53 (effective 1 January 2009 according to res. 27 June 2008 no. 745), 21 June 2013 no. 78 (effective 1 July 2013 according to res. 21 June 2013 no. 702 ), 19 June 2020 no. 78 (in effect 1 July 2020).

## § 2-3 a. *Age limit for assisted fertilization*

A woman who is to receive assisted fertilization cannot be older than the age of 46 at the time of insemination or insertion of a fertilized egg.

0 Added by Act 19 June 2020 No. 78 (with effect from 1 July 2020).

## § 2-4. *Conditions for fertilization outside the body*

Fertilization outside the body can only take place if a woman or a man is unable to conceive or in the case of an unexplained inability to conceive, or when the woman herself has or is a carrier of a serious hereditary disease.

0 Amended by law 25 June 2004 no. 45 (effective 1 September 2004 according to res. 25 June 2004 no. 986), 15 June 2007 no. 31 (effective 1 January 2008 according to res. 15 June 2007 no. 632 ), 27 June 2008 no. 53 (in effect 1 January 2009 according to res. 27 June 2008 no. 745), 19 June 2020 no. 78 (in effect 1 January 2021).

## § 2-5. *Information and consent*

The woman and her possible spouse or cohabitant must be given information about the treatment and about the medical and legal effects the treatment may have. The information must also include information about adoption.

Before the treatment begins, the attending physician must ensure that written consent is given from the woman and her possible spouse or cohabitant. In the case of repeated treatments, new consent must be obtained. Only persons over the age of 18 who have not been deprived of legal capacity to act in the personal area can give such consent.

When the treatment takes place using eggs from the woman who have been fertilized with donated sperm, and the woman has a new spouse or cohabitant, consent to treatment must be given by the woman and her current spouse or cohabitant. Consent from a former spouse or cohabitant is not required, not even if the woman is to use the egg for assisted fertilization as a single person.

0 Amended by law 27 June 2008 no. 53 (in effect 1 January 2009 according to res. 27 June 2008 no. 745), 26 March 2010 no. 9 (in effect 1 July 2013 in accordance with res. 5 April 2013 no. 338 ) as amended by Act 5 April 2013 no. 12, 19 June 2020 no. 78 (with effect from 1 July 2020).

## § 2-6. *Decision on treatment*

The decision to carry out treatment with a view to assisted fertilization is made by a doctor. The decision must be based on medical and psychosocial assessments of the woman and her possible spouse or cohabitant. Emphasis must be placed on the caring capacity of the woman and her possible spouse or cohabitant and consideration for the best interests of the child.

Anyone applying for assisted fertilization must present a child care certificate as mentioned in the Police Register Act § 39 first paragraph.

If it is necessary to supplement the information provided by the woman or the couple themselves, the doctor can obtain relevant information from public bodies in order to make the assessment of the woman's or the couple's ability to care and the best interests of the child in accordance with the first paragraph. Such information can include information about the woman's or the couple's health, finances, housing and how long the couple has lived together. When obtaining information that is subject to a statutory duty of confidentiality, consent is required from the person to whom the information relates.

If the doctor has doubts about the woman's or the couple's ability to care, the doctor can ask for an assessment of the ability to care from an agency determined by the ministry. After receiving the assessment, the doctor decides whether the woman or the couple should receive treatment with assisted reproduction.

The Ministry can issue further regulations on the processing of applications for assisted fertilization.

0 Amended by Act 19 June 2020 No. 78 (with effect from 1 July 2020).

### § 2-7. *Parents' obligation to provide information and the child's right to information about the donor*

Parents who have had a child with the help of a donated unfertilized egg or donated sperm must as soon as possible it is advisable to inform the child about this.

Anyone born after assisted fertilization with the help of a donated unfertilized egg or donated sperm has the right to receive information about the donor's identity at the age of 15. A donor register must assist the child with this. The doctor must inform the woman and her possible spouse or cohabitant about the age from which the child will be able to receive information about the donor's identity.

0 Amended by law 19 June 2020 no. 78 (with effect from 1 July 2020, second paragraph second and third sentence applies), 19 June 2020 no. 78 (with effect from 1 January 2021, new first paragraph and second paragraph first sentence applies. The who were born with the help of sperm donated before the entry into force of the changes in the Biotechnology Act § 2-7 second paragraph, do not have the right to information about the donor's identity until after the age of 18.).

### Section 2-8. *Donor register*

The ministry shall create a register for registering the identity of egg donors and sperm donors, so that the child's right according to § 2-7 can be fulfilled.

0 Amended by Act 19 June 2020 no. 78 (effective 1 January 2021).

### § 2-9. *Egg donor and sperm donor*

A sperm donor must be over 18 years of age and not deprived of legal capacity to act in the personal area.

An egg donor must be over 25 and no older than 35 and not deprived of legal capacity to act on the personal area.

The donor must give written consent for the sperm or the unfertilized eggs to be used fertilization and that his or her identity is registered in the donor register. Consent can be withdrawn until fertilization has taken place.

A sperm donor or egg donor must not be given information about the identity of the woman, the couple or the child.

0 Amended by law 26 March 2010 no. 9 (in effect 1 July 2013 according to res. 5 April 2013 no. 338) as amended by law 5 April 2013 no. 12, 19 June 2020 no. 78 (in effect 1 January 2021 ).

### Section 2-10. *Selection of egg donor and sperm donor*

The attending physician must select a suitable egg donor or sperm donor. The business that carries out the assisted fertilization must ensure that necessary information about the treatment is registered and reported.

0 Amended by Act 19 June 2020 no. 78 (effective 1 January 2021).

### Section 2-11. *Storage and import of unfertilised eggs, ovarian tissue, sperm etc.*

Businesses that have been approved in accordance with § 7-1 can, after approval, import and store unfertilized eggs and sperm. Approval is also required for the storage of ovarian tissue.

Storage that is not specifically medically justified is not covered by the right to health care in Chapter 2 of the Patient and User Rights Act or the responsibility of the public health service to provide health services. A full out-of-pocket payment may be required for such storage.

Businesses that store unfertilized eggs or sperm that have been donated must ensure that information about the egg donor's and sperm donor's identity is registered and reported to a donor register.

Eggs or sperm must not be handed over for use in assisted fertilization after the donor's death, with the exception of fertilized eggs and sperm in cases covered by § 2-17.

Upon the woman's death, stored unfertilized eggs and stored ovarian tissue must be destroyed.

0 Amended by Act 19 June 2020 no. 78 (with effect from 1 July 2020, first, second and fifth paragraphs apply), 19 June 2020 no. 78 (with effect from 1 July 2020 according to res. 19 June 2020 no. 1274, third and fourth paragraphs apply).

### Section 2-12. *Regulations*

In regulations, the Ministry can provide further rules on the organization of egg and sperm banks, the use of donor eggs and donor sperm, as well as the registration and notification of information about egg and sperm donors.

0 Amended by Act 19 June 2020 no. 78 (effective 1 January 2021).

### Section 2-13. *Treatment of sperm before fertilization*

Treatment of sperm before fertilization to influence the choice of the child's sex is only permitted if the woman is a carrier of a serious hereditary sex-linked disease.

### Section 2-14. *Training and quality assurance*

Unfertilized eggs that have been retrieved in connection with fertilization outside the body, but which not suitable for this purpose, can be used for training in and quality assurance of established methods for assisted fertilization. The eggs must be destroyed after the end of the experiment.

Surplus fertilized eggs can be used for training in and quality assurance of established methods for assisted fertilization and preimplantation diagnostics. The conditions for research on excess fertilized eggs in section 3-2 second, third and fourth paragraphs apply accordingly.

Unfertilized and fertilized eggs as mentioned in the first and second paragraphs can only be used for training and quality assurance after voluntary, express and informed consent from the woman or couple receiving fertility treatment. Voluntary, express and informed consent must also be obtained from the sperm or egg donor if donor sperm or donor eggs are used.

0 Amended by law 25 June 2004 no. 45 (effective 1 September 2004 according to res. 25 June 2004 no. 986), 15 June 2007 no. 31 (effective 1 January 2008 according to res. 15 June 2007 no. 632 ), 19 June 2020 no. 78 (with effect from 1 July 2020), 19 June 2020 no. 78 (with effect from 1 January 2021, third paragraph second sentence applies).

### Section 2-15. *Application and insertion of fertilized eggs etc*

Fertilized eggs can only be inserted into the uterus of the woman who will be the child's mother.

In the case of assisted fertilization for single women, the egg must be retrieved from the single woman herself.

In the case of assisted fertilization for couples, simultaneous egg and sperm donation or donation of fertilized eggs is not permitted.

In assisted fertilization for a same-sex couple, an egg retrieved from one of the women can is inserted into the other woman's uterus after fertilization. In such cases , section 2-4 does not apply.

The ministry can provide further regulations on the insertion of fertilized eggs into a woman's body by fertilization outside the body.

0 Amended by law 15 June 2007 no. 31 (in accordance with 1 January 2008 according to res. 15 June 2007 no. 632), 19 June 2020 no. 78 (in accordance with 1 Jan 2021), 4 June 2021 No. 53.

### Section 2-16. *Storage of fertilized eggs*

Businesses that are approved under § 7-1 to carry out assisted fertilization may, after approval, store fertilized eggs.

Fertilized eggs must be stored until the woman the egg is to be inserted into is 46 years old. The woman can consent to a shorter storage period.

Based on resource and benefit considerations, the business can set a shorter storage period than that which follows from the second paragraph. The storage period cannot be shorter than five years from the time the egg was fertilized, unless the woman consents to a shorter storage period or the age limit in the second paragraph has been reached.

When the storage period is over, fertilized eggs must be destroyed or handed over for training or quality assurance, cf. § 2-14 or research, cf. chapter 3.

0 Amended by law 15 June 2007 no. 31 (effective 1 January 2008 according to res. 15 June 2007 no. 632), 19 June 2020 no. 78 (effective 1 July 2020), 19 June 2020 no. 78 (effective 1 January 2021, second paragraph applies).

### Section 2-17. *Use of stored sperm from the deceased or eggs fertilized with the deceased's sperm*

Stored sperm from the deceased, or eggs fertilized with the deceased's sperm, can be used for assisted fertilization by the deceased's surviving spouse or cohabitant if it can be documented that it is in line with the deceased's wishes. The surviving spouse or cohabitant must be single, cf. § 2-2, at the time of the insemination or insertion of the fertilized egg. The other conditions for assisted fertilization in the law must be met.

When using fertilized eggs, the egg must originate from the surviving spouse or cohabitant.

The deceased must be considered the child's father according to the Children's Act.

0 Amended by Act 19 June 2020 No. 78 (with effect from 1 July 2020).

### Section 2-18. *Ban on transplantation of organs and tissues that produce gametes*

Transplantation of organs and tissues that produce gametes from one person to another with the purpose of treating infertility is prohibited.

0 Amended by Act 19 June 2020 no. 78 (effective 1 January 2021).

### Section 2-19. *Approval of forms of treatment etc*

Forms of treatment that fall under § 2-1, import of sperm and unfertilized eggs cf. § 2-11, techniques for processing sperm cf. § 2-13, as well as storage of semen, unfertilized eggs, ovarian tissue and fertilized eggs cf. § § 2-11 and 2-16, must be approved by the ministry, and can only be put into use or carried out by establishments approved in accordance with § 7-1.

Before the ministry decides whether approval is to be granted, the application must be submitted to the Biotechnology Council.

0 Amended by law 9 May 2014 no. 15 (in effect 1 June 2014 according to res. 9 May 2014 no. 622), 19 June 2020 no. 78 (in effect 1 July 2020), 19 June 2020 no. 78 (in 1 July 2020 according to res. 19 June 2020 no. 1274, first paragraph applies).

## Chapter 2A. Preimplantation diagnostics, etc

0 The chapter added by Act 15 June 2007 no. 31 (in effect 1 January 2008 according to res. 15 June 2007 no. 632).

### Section 2A-1. *Genetic examination of fertilized eggs*

Preimplantation diagnostics means a genetic examination of fertilized eggs outside the body before insertion into the uterus, including examination of sex.

Preimplantation diagnostics can be offered to couples or singles where one or both are carriers of a serious monogenic or chromosomal hereditary disease and there is a great risk that the disease can be transmitted to a future child.

Preimplantation diagnostics can also be carried out to examine tissue type with the aim of having a child with the same tissue type who can be a stem cell donor for a sibling with a serious, hereditary disease. In such cases, the following conditions must be met:

a. treatment with sibling donation of healthy, compatible stem cells is highly likely suitable for curing a sick sibling
b. consideration for the sick child is assessed against the burdens on a future sibling c. donors born after pre-implantation diagnostics with tissue typing are not subjected to unacceptable intervention.

Preimplantation diagnostics must not be used to map or select other characteristics of the fertilized egg, than what appears in the paragraph here.

Fertilized eggs that are selected must not be genetically modified.

0 Added by law 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), amended by law 19 June 2020 No. 78 (with effect from 1 July 2020).

### Section 2A-2. *Consent*

Before preimplantation diagnostics are carried out, the woman or the couple must give written informed consent.

0 Added by law 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), amended by law 19 June 2020 No. 78 (with effect from 1 July 2020).

### Section 2A-3. *Information and genetic guidance*

The woman or the couple must receive neutral information and genetic guidance, including information about the risks associated with the treatment, the burden on the woman and the probability of success with the treatment.

0 Added by law 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), amended by law 19 June 2020 No. 78 (with effect from 1 July 2020).

### Section 2A-4. *General conditions for assisted fertilization*

The general rules for fertilization outside the body in Chapter 2 of the Act here also apply for couples and single women seeking preimplantation diagnostics. The requirement of inability to conceive in § 2-4 does not apply.

0 Added by law 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), amended by law 19 June 2020 No. 78 (with effect from 1 July 2020).

### Section 2A-5. *Approval and reporting obligation*

Pre-implantation diagnostics can only take place at establishments approved by the ministry to carry out such treatment. In the decision, the ministry can set further conditions for the approval.

Businesses that have been approved according to the first paragraph must submit a written report to the ministry about the business. The ministry lays down detailed rules on the reporting obligation.

0 Added by Act 15 June 2007 No. 31 (effective 1 January 2008 in accordance with Res. 15 June 2007 No. 632), amended by Act 19 June 2020 No. 78 (effective 1 July 2020), former section 2A-8 .

### Section 2A[1]-6. *(Repealed)*

0 Added by law 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), amended by law 24 June 2011 no. 30 (with effect from 1 January 2012 according to res. 16 Dec. 2011 no. 1252), repealed by Act 19 June 2020 no. 78 (with effect from 1 July 2020).
**Amended** by Act 4 Dec 2020 no. 134 (in force 1 Jan 2021 according to res. 4 Dec 2020 no. 2622).

1 The paragraph was repealed before the amendment by Act 4 Dec 2020 No. 134 came into force.

### Section 2A-7. *(Repealed)*

0 Added by law 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), repealed by law 19 June 2020 No. 78 (with effect from 1 July 2020).

### Section 2A-9. *(Repealed)*

0 Added by Act 11 Dec 2015 No. 97 (in effect 1 Nov 2016 according to Res. 17 June 2016 No. 727), amended by Act 18 Dec 2015 No. 121 (effective 1 July 2018 according to Res. 6 Apr 2018 No. 553), repealed by Act 19 June 2020 No. 78 (effective 1 July 2020).

# Chapter 3. Research on excess fertilized eggs, cloning etc

0 Heading amended by Act 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632).

## Section 3-1. *Use of excess fertilized eggs for research*

Supernumerary fertilized eggs and cells derived from supernumerary fertilized eggs can only used for research when the purpose is:

1. to develop and improve methods and techniques for fertilization outside the body in order to achieve pregnancy
2. to develop and improve methods and techniques for genetic examination of fertilized eggs with a view to determining whether there is a serious monogenic or chromosomal hereditary disease (preimplantation diagnostics)
3. to obtain new knowledge with a view to future treatment of serious disease in humans.

0 Amended by Act 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632).

## Section 3-2. *Conditions for the use of excess fertilized eggs for research*

Research as mentioned in § 3-1 is only permitted on fertilized eggs that have become redundant after fertilization outside the body with a view to fertility treatment or pre-implantation diagnostics.
It is not permitted to fertilize eggs for research purposes alone.

Research on fertilized eggs can be carried out up to 14 days after the egg was fertilized. The egg should destroyed within 14 days after fertilization. The time that fertilized eggs are stored frozen is not included.

Fertilized eggs that have been the subject of research, and gametes that have been the subject of research for research, must not be inserted into a woman, but must be destroyed.

Research that results in genetic changes that can be inherited in humans is not permitted.

0 Added by law 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), amended by law 19 June 2020 No. 78 (with effect from 1 July 2020).

## Section 3-3. *Ethical assessment and approval*

Research, including clinical research, which entails the use of excess fertilized eggs and cells originating from supernumerary fertilized eggs must be approved by the regional committee for medical and healthcare research ethics.

Forms of treatment that require the use of cells from excess fertilized eggs must be approved by the ministry. The Ministry can set further conditions in the approval decision.

Before the ministry decides whether approval under the second paragraph is to be granted, the application must be submitted to the Biotechnology Council.

0 Added by law 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), amended by law 9 May 2014 no. 15 (with effect from 1 June 2014 according to res. 9 May 2014 no. 622).

**§ 3-4.** ***Information and consent***

Surplus fertilized eggs can only be used for research and treatment after the voluntary, express and informed consent of the woman or couple receiving assisted fertilization. Before consent is given, the woman or the couple must receive information about what the research may entail, how it will be carried out and other relevant information.

If fertilization is carried out with donor eggs or donor sperm, the donor must also give voluntarily, express and informed consent. The donor's consent must be obtained in connection with the donation.

Consent can be withdrawn in line with the rules in Section 14 of the Biobank Act.

0 Added by law 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), amended by law 19 June 2020 No. 78 (with effect from 1 July 2020), 19 June 2020 No. 78 (with effect from 1 January 2021, second paragraph applies).

**§ 3-5.** ***Ban on the production of human embryos by cloning etc***

It is prohibited: a.
to produce human embryos by cloning, b. to conduct
research on human embryos and cell lines grown from human embryos produced by cloning and

c. to produce embryos by cloning by inserting human genetic material into an egg cell from animals.

Cloning refers to techniques for producing genetically identical copies.

0 Amended by Act 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), former section 3-2.

**§ 3-6.** ***Prohibition on the use of techniques with the aim of producing genetic similarities individuals***

The use of techniques aimed at producing genetically identical individuals is prohibited.

0 Amended by Act 15 June 2007 no. 31 (in force 1 January 2008 according to res. 15 June 2007 no. 632), former section 3-3.

# Chapter 4. Fetal diagnosis

**Section 4-1.** ***Definition***

In this Act, fetal diagnosis means examination of fetal cells, a fetus or a pregnant woman with the aim of obtaining information about the fetus's genetic characteristics or to detect or rule out disease or developmental abnormalities in the fetus.

Ultrasound examinations in general prenatal care are not considered fetal diagnostics according to the first paragraph, and are therefore not covered by this Act with the exception of § 4-5.

**Section 4-2.** ***Approval of fetal diagnostics***

Examination methods that fall under section 4-1 first paragraph must be approved by the ministry.

0 Amended by law 9 May 2014 no. 15 (in effect 1 June 2014 according to res. 9 May 2014 no. 622), amended by law 19 June 2020 No. 78 (with effect from 1 July 2020).

### Section 4-3. *Consent*

Before fetal diagnosis, cf. § 4-1 , is carried out, the person to be examined must give written consent.

### Section 4-4. *Information and genetic guidance*

In the case of fetal diagnosis, the woman or the couple must be given information such as, before the examination other must include that the examination is voluntary, what risks are associated with carrying out the examination, what the examination may uncover and what consequences this may have for the child, the woman, the couple and the family. If genetic disease is suspected, the woman or the couple must also be given genetic counselling.

If the examination shows that the fetus may have a disease or developmental abnormality, the woman must or the couple is provided with information and genetic guidance about the disease or disability in question, as well as about applicable rights and relevant support measures.

### § 4-5. *Information about gender before the 12th week of pregnancy*

Information about the sex of the fetus before the 12th week of pregnancy, which is revealed by fetal diagnosis or other examination of the fetus, must only be given if the woman is a carrier of a serious sex-linked disease.

### § 4-6. *Paternity testing in the fetal stage*

Fetal diagnostics with the aim of determining paternity and paternity testing at the fetal stage are prohibited. This does not apply when the pregnancy may be the result of circumstances as mentioned in the Criminal Code §§ 291, 295, 296, 299 letter a, 302, 312, 313 and 314 letter a.

0 Amended by Act 19 June 2015 no. 65 (in force 1 October 2015).

## Chapter 4A. Use of fetal tissue

0 The heading added by Act 7 May 2015 no. 25 (in effect 1 January 2016 according to res. 13 November 2015 no. 1289).

### Section 4A-1. *Definition*

In this Act, fetal tissue means cells and tissue from induced abortions.

0 Added by Act 7 May 2015 no. 25 (in effect 1 Jan 2016 according to res. 13 Nov 2015 no. 1289).

### Section 4A-2. *Use of fetal tissue*

Fetal tissue can only be used for medical research, diagnostics, vaccine production and treatment.

The use of fetal tissue for treatment is only permitted in cases where there is a serious illness or injury and other forms of treatment have limited effect. The use of fetal tissue for medical research, diagnostics and vaccine production is only permitted if there are no other equivalent methods.

It is prohibited to use ovarian tissue from induced abortion fetuses for transplantation.

The commercial exploitation of cells and tissues from aborted fetuses is prohibited.

0 Added by Act 7 May 2015 no. 25 (in effect 1 Jan 2016 according to res. 13 Nov 2015 no. 1289).

### Section 4A-3. *Approval*

Use of fetal tissue for treatment and research must be approved by the ministry.

0 Added by Act 7 May 2015 no. 25 (in effect 1 Jan 2016 according to res. 13 Nov 2015 no. 1289).

### Section 4A-4. *Consent*

Written consent from the woman must be obtained before fetal tissue can be submitted to a fetal tissue bank.

Only after the decision to terminate the pregnancy has been made can the woman be informed of the possibility use of fetal tissue. Consent can only be validly given after such information has been provided.

0 Added by Act 7 May 2015 no. 25 (in effect 1 Jan 2016 according to res. 13 Nov 2015 no. 1289).

### Section 4A-5. *Fetal tissue bank*

All collection, storage and delivery of fetal tissue must be carried out by a fetal tissue bank. Fetal tissue banks must be approved by the ministry.

The Ministry can, in regulations, issue supplementary rules on fetal tissue banks' collection, storage and delivery of fetal tissue.

0 Added by Act 7 May 2015 no. 25 (in effect 1 Jan 2016 according to res. 13 Nov 2015 no. 1289).

### Section 4A-6. *Anonymity*

The woman must not be given information about the identity of the person receiving the fetal tissue.

The recipient of fetal tissue must not be given information about the identity of the woman who donated it the fetal tissue.

0 Added by Act 7 May 2015 no. 25 (in effect 1 Jan 2016 according to res. 13 Nov 2015 no. 1289).

### Section 4A-7. *Information*

Anyone who receives fetal tissue for transplantation must be informed that the tissue originates from unprovoked aborted foetuses.

0 Added by Act 7 May 2015 no. 25 (in effect 1 Jan 2016 according to res. 13 Nov 2015 no. 1289).

### Section 4A-8. *Right of reservation*

Healthcare personnel who, for reasons of conscience, wish to do so may reserve the right to participate in research projects where fetal tissue is used and to carry out or assist in the transplantation of fetal tissue.

0 Added by Act 7 May 2015 no. 25 (in effect 1 Jan 2016 according to res. 13 Nov 2015 no. 1289).

## Chapter 5. Genetic examinations of births etc

### Section 5-1. *Definition*

In this act, genetic research means all types of analysis of human genetic material, both at nucleic acid and chromosomal level, of gene products and their function, or organ examinations, which are intended to provide information about human hereditary characteristics.

In this Act, genetic examinations of newborns mean: a. genetic examinations where the purpose of the examination is to diagnose a disease. b. genetic presymptomatic examinations, genetic predictive examinations and genetic examinations to detect or rule out carrier status for hereditary diseases that only appear in later generations.

c. genetic laboratory examinations to determine gender, except genetic laboratory tests for identification purposes.

0 Amended by Act 19 June 2020 No. 78 (with effect from 1 July 2020).

### Section 5-2. *Application of genetic investigations*

Genetic tests must only be used for medical purposes with diagnostic or treatment objectives.

### Section 5-3. *(Repealed)*

0 Amended by law 9 May 2014 no. 15 (in effect 1 June 2014 according to res. 9 May 2014 no. 622), repealed by law 19 June 2020 No. 78 (with effect from 1 July 2020).

### Section 5-4. *Consent*

Before genetic examination covered by § 5-1 second paragraph letter b is carried out, the person to be examined must give written consent to the examination.

Before a genetic examination covered by § 5-1 second paragraph letter b is carried out on children under the age of 16, written consent must be given from the child's parents or others with parental responsibility.

## Section 5-5. *Genetic guidance*

In the case of genetic examinations according to Section 5-1, second paragraph, letter b, the person being examined must be given adapted genetic guidance.

If the person examined is a child under the age of 16, genetic guidance must also be given to the child's parents or others with parental responsibility.

0 Amended by Act 19 June 2020 No. 78 (with effect from 1 July 2020).

## § 5-6. *Mass genetic studies and pharmacogenetic studies*

The King can issue regulations on the approval of mass genetic tests and pharmacogenetic tests. In the regulations, exceptions can be made to the law's requirements for written consent, genetic counselling, approval of activities or reporting.

## § 5-7. *Genetic examination of children*

Genetic testing covered by Section 5-1, second paragraph, letter b, must not be carried out on children before the child is 16 years old, unless the examination can demonstrate conditions which, through treatment, can prevent or reduce damage to the child's health.

In special cases, the ministry can make exceptions to the prohibition in the first paragraph.

## § 5-8. *Prohibition on the use of genetic information outside the health and care services*

It is prohibited to request, receive, possess, or use genetic information about another person which has been revealed by genetic examinations covered by Section 5-1, second paragraph, letter b, or by systematic mapping of hereditary disease in a family. The same applies to genetic information about the risk of future disease that has emerged from genetic examinations covered by section 5-1, second paragraph, letter a.

It is forbidden to ask whether genetic research or systematic mapping of hereditary disease in a family has been carried out.

The prohibition in the first and second paragraphs does not cover businesses that have been approved in accordance with section 7-1 to carry out genetic investigations covered by § 5-1 second paragraph, or for research purposes.
If genetic information is to be used for research purposes, the person to whom the information relates must have given consent to this.

The prohibition in the first paragraph does not apply to private individuals who act on behalf of or with the consent of the person to whom the information relates.

Exempted from the prohibition in the first and second paragraphs are healthcare personnel who need the information in for diagnostic and treatment purposes.

0 Amended by law 24 June 2011 no. 30 (in effect 1 Jan 2012 according to res. 16 Dec 2011 no. 1252), 19 June 2020 no. 78 (effective 1 July 2020).

### § 5-9. *Outreach genetic information activities*

In this act, outreach genetic information activities are understood to be those of healthcare personnel access to inform the patient's affected relatives about a hereditary disease in the family.

When it has been documented that a patient has or is predisposed to a hereditary disease, the patient decides for himself whether he or she wants to inform affected relatives about this.

If the patient himself cannot or does not want to inform affected relatives, healthcare personnel can ask on the patient's consent to inform them, if the conditions in the fifth paragraph are met and the disease has been approved by the ministry in accordance with the seventh paragraph.

If the patient cannot consent to healthcare personnel informing affected relatives, healthcare personnel may in special cases do this, if the conditions in the fifth paragraph are met and the disease has been approved by the ministry in accordance with the seventh paragraph.

Before health personnel make contact with the relatives, he or she must assess whether: 1. it concerns an illness with significant consequences for the individual's life or health, 2. there is a reasonable degree of probability that the relatives also have a hereditary disease predisposition that can lead to illness later in life, 3. there is a documented connection between the hereditary disease predisposition and development of the disease, 4. the genetic tests used to determine the hereditary predisposition to the disease are reliable, and 5. the disease can be prevented or treated with good effect.

If the relative is under 16, only the parents or others with parental responsibility must be informed.

The ministry determines in regulations or in individual cases which diseases can are made the subject of outreach genetic activities.

## Chapter 6. Gene therapy

### Section 6-1. *Definition*

In this Act, gene therapy means medicinal products that are covered by the definition in Regulation on Advanced Therapies (EU) No. 1394/2007 Article 2, cf. Directive 2001/83 (the Medicines Directive) Annex 1 Part IV Section 2.1.

0 Amended by Act 19 June 2020 No. 78 (with effect from 1 July 2020).

### Section 6-2. *Conditions for gene therapy etc.*

Gene therapy can only be used to treat disease or to prevent disease from occurring.

Gene therapy and other transfer of genetic material to human cells, fetuses and fertilized animals eggs that cause genetic changes that are inherited in gametes are prohibited.

0 Amended by Act 19 June 2020 No. 78 (with effect from 1 July 2020).

**Section 6-3.** ***(Repealed)***

0 Amended by law 9 May 2014 no. 15 (in effect 1 June 2014 according to res. 9 May 2014 no. 622), repealed by law 19 June 2020 No. 78 (with effect from 1 July 2020).

**Section 6-4.** ***Consent***

Before gene therapy is initiated, the person to be treated must give written consent. Before gene therapy is initiated on children under the age of 16, written consent must be given from the parents or others with parental responsibility.

# Chapter 7. General provisions

**Section 7-1.** ***Approval of businesses***

Medical use of biotechnology etc. that requires approval in accordance with §§ 2-19, 3-3 second paragraph, 4-2 and medical use of biotechnology in accordance with § 5-1 second paragraph letter b, can only take place at establishments that have been specially approved by the ministry for the relevant purpose. It must be stated in the approval decision which forms of medical biotechnology the business is permitted to carry out or requisition.

The Ministry can set further conditions for approval in the approval decision.

0 Amended by law 15 June 2007 no. 31 (in accordance with 1 January 2008 according to res. 15 June 2007 no. 632), 19 June 2020 no. 78 (in accordance with 1 July 2020).

**Section 7-2.** ***Reporting obligation***

Any business that is approved in accordance with § 7-1 must give a written report to the ministry about the business.

The ministry lays down detailed rules on the reporting obligation.

**Section 7-3.** ***The Biotechnology Council***

The King appoints a council which, on request or on its own initiative, can issue statements in matters under this Act and in other matters relating to biotechnology. The council's statements are public, unless otherwise follows from a statutory duty of confidentiality.

The King can issue further regulations on the council's activities and composition.

0 Amended by Act 9 May 2014 no. 15 (in effect 1 June 2014 according to res. 9 May 2014 no. 622).

**Section 7-4. *Regulations***

The King can, by regulation, lay down further provisions for the completion and implementation of the Act.

**Section 7-5. *Penalty***

Anyone who violates the law or regulations issued pursuant to the law is punished with fines or imprisonment for up to three months.

The first paragraph does not apply to: a. private individuals who apply for or use offers that are in breach of this Act, b. those who donate eggs, sperm or fertilized eggs or c. research participants.

The first subsection does not apply to violations of section 2-7 first subsection.

0 Amended by law 21 June 2013 no. 78 (effective 1 July 2013 according to res. 21 June 2013 no. 702), 19 June 2015 no. 65 (effective 1 October 2015), 19 June 2020 no. 78 (effective . 1 July 2020).

**Section 7-6. *Entry into force and transitional arrangements***

The law enters into force from the time the King decides. The king can put the individual ones into effect[1] provisions in the law at different times.

Decisions made pursuant to Act 5 August 1994 no. 56 on the medical use of biotechnology shall continue to apply as long as they do not conflict with the Act here, or with regulations or individual decisions made pursuant to this Act.

1 From 1 January 2004 according to res. 19 Dec 2003 no. 1591, with the exception of section 2-7 to section 2-12, chapter 4 and section 7-7 no. 1 regarding the repeal of Act of 5 August 1994 no. 56 on the medical use of biotechnology § 2-5 to § 2-7 , chapter 5 and chapter 8.

According to res. 25 June 2004 no. 985 , Section 2-8, Section 2-9, Section 2-11 and Section 2-12 shall apply from 1 September 2004, Section 2-7, Section 2-10 and Chapter 4 shall apply from 1 January 2005, and the provision § 7-7 No. 1 on the repeal of Act 5 Aug 1994 No. 56 on the medical use of biotechnology shall apply from 1 January 2005. The repeal of § 2-7 in the Act on the Medical Use of Biotechnology applies, however, from 1 Sep 2004 .

**Section 7-7. *Changes in other laws***

From the time the Act enters into force, other Acts are amended as follows: – – –