

Note: this is not an official translation**Federal Law
on Human Genetic Testing
(LHGT)**

of 8 October 2004 (as of 1 April 2007)

The Federal Assembly of the Swiss Confederation,

in accordance with Article 98 para. 3, 110 para. 1, 113 para. 1, 117 para. 1, 119 para. 2 f, 122 para. 1 and 123 para. 1 of the Federal Constitution¹, and having considered the Message of the Federal Council of 11 September 2002²,

decrees:

Chapter 1: Scope, purpose and definitions**Article 1** Scope

¹ This law stipulates the conditions under which human genetic testing may be carried out:

- a. in the medical context;
- b. in the context of employment;
- c. in the context of insurance;
- d. in the context of liability.

² It also regulates the creation of DNA profiles for the purpose of determining the filiation or identity of an individual. The DNA Profile Law of 20 June 2003³ applies to the use of DNA profiles in criminal proceedings and for the purpose of identifying unknown or missing persons.

³ Unless otherwise stipulated elsewhere in this text, this law does not apply to genetic testing carried out for research purposes.

Article 2 Purpose

This law aims:

- a. to protect human dignity and personality;
- b. to prevent improper genetic testing and the improper use of genetic data;
- c. to ensure the quality of genetic tests and the way their results are interpreted.

¹ SR 101

² BBl 2002 7361

³ SR 363

Article 3 Definitions

For the purpose of this law, the following definitions shall apply:

- a. *genetic tests*: cytogenetic and molecular genetic tests to determine hereditary characteristics of human genetic material or characteristics of human genetic material acquired during the embryonic phase, and all other laboratory tests whose immediate purpose is to provide such information about genetic material;
- b. *cytogenetic tests*: tests to determine the number and structure of chromosomes;
- c. *molecular genetic tests*: tests to determine the molecular structure of nucleic acids (DNA and RNA) and the immediate gene product;
- d. *presymptomatic genetic tests*: genetic tests whose purpose is to identify predisposition to disease before clinical symptoms emerge, with the exception of tests designed solely to determine the effect of a planned therapy;
- e. *prenatal tests*: prenatal genetic testing and prenatal risk assessment;
- f. *prenatal genetic tests*: genetic tests during pregnancy to determine characteristics of the genetic material of the embryo or fetus;
- g. *prenatal risk assessment*: laboratory tests which provide information about the risk of the embryo or fetus having a genetic anomaly, and investigations of the embryo or fetus using imaging techniques;
- h. *testing for family planning purposes*: genetic tests to determine a genetic risk for future offspring;
- i. *screening*: genetic tests offered systematically to the entire population or to certain groups of individuals in the population without there being a suspicion that the individual may have the characteristics being sought;
- j. *genetic in vitro diagnostic devices*: ready-to-use products for the determination of hereditary characteristics ;
- k. *DNA profile*: information specific to an individual which is obtained from the non-coding sequences of their DNA using molecular genetic techniques;
- l. *genetic data*: information about the genetic material of a person that is obtained from a genetic test, including their DNA profile;
- m. *sample*: biological material collected for a genetic test;
- n. *person concerned* a person whose genetic material is tested or for whom a DNA profile is created and from whom corresponding samples or genetic data exist; in the context of prenatal testing: the pregnant woman.

Chapter 2: General principles for genetic testing

Article 4 Non-discrimination

No-one may be discriminated against on the basis of his genetic material.

Article 5 Consent

¹ Genetic and prenatal testing, including screening, may not be carried out unless the affected person has been provided with adequate information about the testing and has given his voluntary consent. This shall not apply to exceptions stipulated in a federal law.

² If the affected person is incapable of giving consent, that person's legal representative shall provide consent on his behalf. In the medical context the limitations of Article 10 para. 2 must be observed.

³ Consent may be withdrawn at any time.

Article 6 Right not to know

Every person has the right to refuse to receive information about his genetic status subject to Article 18 para. 2.

Article 7 Protection of genetic data

The processing of genetic data is subject to:

- a. professional secrecy as stipulated in Articles 321 and 321a of the Penal Code⁴; and
- b. federal and cantonal data protection regulations.

Article 8 Authorisation to perform genetic testing

¹ Any person who wishes to perform cytogenetic or molecular genetic tests requires authorisation from the competent federal authority.

² The Federal Council:

- a. nominates the competent federal authority;
- b. regulates the requirements and the procedure for granting the authorisation;
- c. defines the duties of the holder of the authorisation;
- d. regulates oversight and, in particular, makes provision for unannounced inspections;
- e. determines the fees.

³ The Federal Council may, having consulted the Expert Commission on Human Genetic Testing (Article 35):

⁴ SR 311.0

- a. require authorisation to be obtained for other genetic tests or prenatal risk assessment if these have to fulfil the same requirements in terms of quality assurance and interpretation of their results as cytogenetic and molecular genetic tests;
- b. exempt from the requirement for authorisation genetic tests which do not need to fulfil any special requirements in terms of performance and interpretation of their results.

⁴ DNA profiles in the sense of this law may only be determined by laboratories recognised by the federal government. The Federal Council regulates the requirements and the procedure for recognising such laboratories and for oversight.

Article 9 Genetic in vitro diagnostic devices

¹ It is forbidden to supply genetic in vitro diagnostic devices to individuals for a purpose which cannot be considered part of those individuals' professional or commercial activities.

² The Federal Council may, having consulted the Expert Commission on Human Genetic Testing, make provision for exceptions to this prohibition provided the products are used under medical supervision and misinterpretation of the test result is not possible.

Chapter 3: Genetic testing in the medical context

Article 10 Genetic testing of individuals

¹ Genetic tests may only be performed on individuals if they serve a medical purpose and the right to self-determination according to Article 18 is ensured.

² A genetic test may only be carried out on a person incapable of judgment if the test is necessary to protect that person's health. Exceptionally, a test of this kind is permissible if there is no other way of identifying a severe hereditary disorder in the family or a corresponding predisposition and the burden on the affected person is minimal.

Article 11 Prenatal tests

It is forbidden to carry out prenatal tests whose purpose is:

- a. to determine characteristics of the embryo or fetus which do not directly impair its health; or
- b. to determine the sex of the embryo or fetus for a purpose other than diagnostic.

Article 12 Screening

¹ Screening may only be performed if the programme has been authorised by the competent federal authority.

² Authorisation can be granted if:

- a. early treatment or prophylaxis is possible;
- b. the test method has been shown to produce reliable results; and
- c. appropriate genetic counselling is provided.

³ Before the competent federal authority issues the authorisation, it consults the Expert Commission on Human Genetic Testing and, where necessary, the Swiss National Advisory Commission on Biomedical Ethics.

⁴ The Federal Council may make provision for further conditions. It designates the competent federal authority and regulates the procedure for issuing authorisations, oversight and fees.

Article 13 Right to prescribe genetic tests

¹ Genetic tests may only be prescribed by medical doctors who are authorised to practice their profession independently or under the supervision of such.

² Presymptomatic and prenatal genetic tests and tests carried out for the purpose of family planning may only be ordered by doctors who have received appropriate post-graduate training or who, during their post-graduate training, work under the supervision of doctors who have received appropriate post-graduate training.

³ The doctor who orders a genetic test under the terms of para. 2 ensures that the person concerned receives genetic counselling.

Article 14 Genetic counselling in general

¹ Presymptomatic and prenatal genetic tests and tests for the purpose of family planning must be preceded and followed by non-directive genetic counselling provided by a qualified person. The counselling session must be documented.

² Counselling must address only the individual and family situation of the affected person; it must not take public interest into consideration. It must take into account the possible psychological and social impact of the test results on the affected person and his family.

³ The affected person or, if he is not capable of giving consent (or if not capable to discern?), his legal representative must be informed specifically of:

- a. the purpose, nature and significance of the test and of any complementary measures;
- b. any risks which may be associated with the test and the frequency and nature of the disorder being diagnosed;
- c. the possibility of an unexpected test result;
- d. the possible physical and psychological burden;

- e. third-party payment options for the cost of the test and of subsequent measures;
- f. support available in connection with the test result;
- g. the severity of the anomalies which may be detected and the possible therapeutic and prophylactic measures.

⁴ A sufficient period of time for reflection must be allowed between the counselling session and the test .

⁵ In screening testing the counselling is adapted according to the circumstances.

Article 15 Genetic counselling for prenatal genetic tests

¹ The pregnant woman must be informed expressly about her right to self-determination both before and after a prenatal genetic test.

² The woman must be made aware if there is a high probability that the proposed test will not lead to any therapeutic or prophylactic options ; she must also be informed of the opportunity to contact an information and counselling centre for prenatal testing.

³ If a severe, incurable disorder is detected, the woman must also be informed about alternatives to termination of the pregnancy and made aware of the existence of associations of parents of disabled children and self-help groups.

⁴ The woman's husband or partner should be involved in the genetic counselling if possible.

Article 16 Information in connection with prenatal risk assessment

Before a laboratory test which aims to evaluate the risk of a genetic anomaly of the embryo or fetus and before any prenatal ultrasound investigation, the woman must be informed of the following:

- a. the purpose and significance of the test;
- b. the possibility of unexpected test results;
- c. the possible complementary tests and interventions; and
- d. information and counselling centres as defined in Article 17.

Article 17 Information and counselling centres for prenatal testing

¹ The cantons shall ensure that there are independent information and counselling centres for prenatal testing, with personnel with the required competency..

² They may set up centres of this kind jointly or delegate their tasks to the recognised pregnancy advisory centres (Federal Law concerning Pregnancy Advisory Centres of 9 October 1981⁵).

³ These centres provide general information and counselling on prenatal testing and, if requested to do so, put clients in touch with associations of parents of disabled children or self-help groups.

Article 18 The concerned person's right of self-determination

¹ Having been provided with adequate information, the affected person is free to decide:

- a. whether to undergo a genetic or prenatal test and, where relevant, a subsequent test;
- b. whether to be informed of the result of the test; and
- c. of the subsequent use of the test result.

² The doctor must immediately transmit the test result to the person concerned if he is aware of an immediate physical danger to the person, to the embryo or to the fetus, which could be averted.

³ Consent for presymptomatic or prenatal genetic testing and for tests carried out for family planning purposes must be obtained in writing, with the exception of screening tests.

⁴ If the affected person is not capable of discernment, his legal representative shall decide.

Article 19 Disclosure of genetic data

¹ The doctor may disclose genetic test results only to the person concerned or, if he is not capable of discernment, to his legal representative.

² If the affected person gives his express consent, the doctor may disclose the test result to the person's family members, spouse or partner.

³ If the person withholds his consent, the doctor may apply to the competent cantonal authority as stipulated in Article 321 section 2 of the Penal Code⁶ to be released from his duty of professional secrecy, should the protection of the overriding interests of the family members, spouse or partner require that they receive this information. The authority may request an opinion from the Expert Commission on Human Genetic Testing.

Article 20 Further use of biological material

¹ A sample may only be used for further purposes to which the affected person has consented.

⁵ SR 857.5

⁶ SR 311.0

² Genetic tests for research purposes may be carried out (or performed?) on biological material obtained for other purposes provided that it has been anonymized and that the affected person or, if he is not capable of discernment, his legal representative, has been informed of his rights and has not expressly forbidden the use of the material for research purposes.

³ Otherwise the special legal provisions governing research shall apply.

Chapter 4: Genetic testing in the context of employment

Article 21 Principle

At hiring and during a professional relationship, the employer and his medical consultant may not:

- a. require presymptomatic genetic tests to be carried out (or to be performed?);
- b. require the results of prior presymptomatic genetic tests to be disclosed nor make use of such results;
- c. require genetic tests to be carried out with the intention of detecting personal characteristics of the employee which do not relate to his health.

Article 22 Exceptions for presymptomatic genetic tests to prevent occupational diseases and accidents

At hiring and during a professional relationship, the occupational health or designated doctor may order a presymptomatic genetic test if the following conditions are met:

- a. The Swiss Accident Insurance Fund (SNAIF) has ruled that the post is subject to occupational health monitoring, or other federal regulations require the employee to undergo a medical examination to ascertain his suitability for the job because there is a danger of an occupational disease or severe environmental contamination occurring or there is a serious risk of accident or health hazards for third parties.
- b. Workplace-related measures within the meaning of Article 82 of the Federal Law concerning Accident Insurance of 20 March 1981⁷ or other legal provisions are not sufficient to preclude these risks.
- c. Available scientific knowledge has established a causal relationship between a specific genetic predisposition and occupational disease, danger of environmental contamination or a risk of accident or health hazards to third parties.

⁷ SR 832.20

- d. The Expert Commission for Human Genetic Testing has confirmed the report of the association and has deemed the type of test to be reliable in identifying the relevant genetic predisposition.
- e. The affected person has given his written consent to the test.

Article 23 Performance of the test

¹ The test can only address the genetic predisposition relevant to the particular post. Attempting to acquire other genetic data is forbidden.

² Genetic counselling as stipulated in Article 14 must be provided before and after the test.

³ The sample must be destroyed on completion of the test.

Article 24 Disclosure of the test result and assumption of the costs

¹ The doctor transmits the result of the test to the person concerned. The employer is only informed whether the person concerned can or cannot be considered for the intended activity.

² If the occupational health examination is mandated by SNAIF, this body pays for the test; in other cases the employer bears the costs.

Article 25 Regulatory intervention

If the executive bodies designated by the Labour Law of 13 March 1964⁸ or the Federal Law concerning Accident Insurance of 20 March 1981⁹ observe violations of Articles 21-24, they are bound by virtue of their office to intervene.

Chapter 5: Genetic testing in the context of insurance**Article 26** Prohibition of testing

An insurance provider may not require a presymptomatic nor a prenatal genetic test prior to providing insurance.

Article 27 Prohibition of further enquiries

¹ Insurance providers may neither require the disclosure of, nor utilize, pre-existing results of presymptomatic or prenatal genetic tests or tests for family planning purposes, from applicants for the following:

- a. insurance which is subject either in part or as a whole to the terms of the Federal Law of 6 October 2000 concerning the General Part of the Social Insurance Legislation¹⁰;

⁸ SR 822.11

⁹ SR 832.20

¹⁰ SR 830.1

- b. mandatory occupational insurance or voluntary occupational insurance that goes beyond the scope of the mandatory insurance;
- c. insurance relating to the obligation to continue paying the individual's salary in case of illness or maternity;
- d. life insurance with an insured sum up to a maximum of CHF 400,000;
- e. voluntary invalidity insurance with an annuity not exceeding CHF 40,000.

² If an individual takes out several life or invalidity insurance policies, the maximum amount stipulated in para. 1 d or e is valid for the sum of the policies. The applicant must provide the insurance provider with the pertinent information requested.

Article 28 Authorization to require or utilize pre-existing results of a presymptomatic genetic test

¹ Before a private insurance policy not covered by Article 27 is taken out, insurance providers may only require the applicant to disclose to the designated doctor the results of a previously performed presymptomatic genetic test if:

- a. the test in question provides reliable results both technically and in medical practice; and
- b. the scientific value of the test for the calculation of premiums has been demonstrated.

² The designated doctor may inform the insurance provider only of the risk group to which the applicant must be assigned.

³ The designated doctor may only retain the results of the test if they are relevant for the conclusion of the contract.

⁴ The test results must be used solely for the purpose for which they were obtained from the applicant before establishing the contract.

Chapter 6: Genetic testing in the context of liability

Article 29 Prohibition of presymptomatic genetic testing

¹ Performing a presymptomatic genetic test for the purpose of calculating claims or determining compensation is forbidden, except in cases involving a genetic anomaly acquired during the embryonic phase and for which compensation or restitution is being claimed.

² Requesting or utilizing the results of a presymptomatic or prenatal genetic test or a test for family planning purposes, for the purpose of calculating claims or determining compensation, is forbidden.

Article 30 Detection of diseases

A diagnostic genetic test with the aim of calculating claims or determining compensation may only be performed with the written consent of the person concerned or by order of the court.

Chapter 7: DNA profile to determine filiation or identity**Article 31** Principle

¹ DNA profiling to determine origin or for identification purposes must not lead to the determination of information concerning health or other personal characteristics, with the exception of the sex of the person concerned.

² The sample must be taken by the laboratory which will perform the DNA profiling or by a doctor mandated by the laboratory. The person concerned must provide proof of his identity.

³ The samples may not be used for other purposes.

Article 32 Civil proceedings

¹ In civil proceedings DNA profiling of parties or third parties may only be performed by order of the court or with the written consent of the person concerned.

² The samples obtained in the course of the proceedings must be retained by the laboratory. The court which ordered the test ensures that the samples are destroyed immediately after the implementation of the final judgement, unless the person concerned has requested in writing that his samples be retained for a longer period.

Article 33 Administrative proceedings

¹ If in administrative proceedings there are justified doubts about the filiation or the identity of a person which cannot be dispelled in any other way, the competent authority may make the granting of authorisation or benefits conditional to DNA profiling.

² DNA profiling may only be performed with the written consent of the person concerned..

³ The samples must be retained by the laboratory. The authority ensures that the samples are destroyed immediately after the implementation of the decision.

Article 34 Determination of origin outside an administrative process

¹ Outside the context of an administrative process, DNA profiling to determine filiation may be performed only with the written consent of the person concerned; a child incapable of discernment and whose filiation with a particular individual must be determined, may not be represented by that person.

² The laboratory that performs the DNA profiling must, before undertaking the test, inform the person concerned in writing about the provisions of the Civil Code¹¹ concerning the determination of filiation and draw their attention to the possible psychological and social impact of the test.

³ The person concerned or, if he is incapable of discernment, his legal representative, shall decide whether his sample shall be retained or destroyed.

⁴ Prenatal DNA profiling with the aim of determining filiation may not be ordered by a doctor unless the woman has previously had a thorough discussion addressing in particular, her reasons for wanting to perform the test, the risks associated with obtaining the sample, the psychological, social and legal aspects associated with the pregnancy, any subsequent measures that may be taken following the result and the possibility of obtaining support. The counselling session must be documented.

Chapter 8: Expert Commission on Human Genetic Testing

Article 35

¹ The Federal Council shall appoint an Expert Commission for Human Genetic Testing.

² The Expert Commission shall have the following tasks in particular:

- a. To develop standards for the quality control of genetic tests with respect to the granting of authorisations (Article 8 para. 2) and to submit recommendations to the Federal Council on whether certain genetic tests should be exempted from or subjected to the requirement for authorisation (Article 8 para. 3);
- b. To comment on requests for authorisation At the request of the competent federal authority, and to participate in inspections (Article 8 para. 1 and 2);
- c. To make recommendations on whether certain genetic in vitro diagnostic devices should be exempted from the prohibition stipulated in Article 9 para. 1;
- d. To advise on screening programs (Article 12);
- e. Where necessary, to make recommendations on post-graduate training as required by Article 13 para. 2;
- f. To make recommendations on genetic counselling (Article 14 and 15) and information relating to prenatal risk assessment (Article 16);
- g. To advise, on request from the competent cantonal authority, on applications for release from the duty of professional secrecy (Article 19 para. 3);

¹¹ SR 210

- h. To provide confirmations as stipulated in Article 22 d;
- i. To make recommendations on DNA profiling;
- j. To follow the scientific and practical development of genetic testing, to make recommendations and to highlight gaps in the legislation in this field.

³ The Commission shall fulfil its tasks independently.

Chapter 9: Penalties

Article 36 Genetic tests performed without consent

Whosoever deliberately orders or performs a genetic test without obtaining the consent of the person being tested, as required by this law, shall be punished by imprisonment or a fine.

Article 37 Genetic testing without authorisation

Whosoever deliberately carries out a genetic test on a third party without the authorisation stipulated in Article 8 shall be punished by imprisonment or a fine.

Article 38 Supply of genetic in vitro diagnostic products

¹ Whosoever deliberately supplies, in contravention of Article 9 para. 1, genetic in vitro diagnostic devices to an individuals for a purpose which cannot be considered part of that individual's professional or commercial activities shall be punished by imprisonment or a fine.

² If the act is committed for commercial gain, the penalty shall be imprisonment or a fine of up to CHF 100,000.

Article 39 Abuse in the context of employment

Whosoever, in contravention of Article 21 and in the context of employment, deliberately:

- a. requires a presymptomatic genetic test or a genetic test to determine personal characteristics which are not related to health; or
- b. requires disclosure of the results of a prior presymptomatic genetic test or requires or requests asks about them during an employment-related medical examination or makes use of such results.

shall be punished by imprisonment or a fine.

Article 40 Abuse in the context of insurance

Whosoever, in the context of insurance, deliberately:

- a. requires a presymptomatic or a prenatal genetic test in contravention of Article 26, or

- b. requires the disclosure of the results of a prior presymptomatic or prenatal genetic test or of a test for family planning purposes, or requires or utilizes the results of such a test in the context of a medical risk assessment, in contravention of Article 27.
- shall be punished by imprisonment or a fine.

Article 41 Competent authority and administrative penal law

¹ The cantons shall be responsible for the prosecution and assessment of criminal acts under the terms of this law.

² Articles 6 and 7 (offences committed within a company) and 15 (forgery, fraudulent obtention of a false certificate) of the Federal Law of 22 March 1974 concerning Administrative Penal Law¹² shall be applicable.

Chapter 10: Final provisions

Article 42 Authorisation to carry out genetic testing

¹ Whosoever requires an authorisation as stipulated in Article 8 must submit the request to the competent federal authority within three months of this law coming into force.

² Any person who does not submit the request within the deadline must cease his activity.

Article 43 Screening

Screening programs which are underway at the time this law comes into force are not subject to authorisation.

Article 44 Referendum and entry into force

¹ This law is subject to optional referendum.

² The Federal Council shall determine its date of entry into force.

Date of entry into force: 1 April 2007¹³

¹² SR 313.0

¹³ DFC of 14 February 2007 (AS 2007 649)