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Federal Act on Human Genetic Testing (HGTA)

of 8 October 2004 (Status as of 1 April 2007)

The Federal Assembly of the Swiss Confederation,

in accordance with Article 98 paragraph 3, 110 paragraph 1, 113 paragraph 1, 117 paragraph 1, 119 paragraph 2 f, 122 paragraph 1 and 123 paragraph 1 of the Federal Constitution¹,

and having considered the Dispatch of the Federal Council dated 11 September 2002²,

decrees:

Chapter 1: Scope, Purpose and Definitions

Article 1 Scope

¹ This Act stipulates the conditions under which human genetic testing may be performed:

- 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 Profiling Act 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 Act does not apply to genetic testing performed for research purposes.

AS 2007 635

¹ SR 101

² BBI 2002 7361

³ SR 363

Article 2 Purpose

This Act 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.

Article 3 Definitions

In this Act:

- a. *genetic test means* 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 means* tests to determine the number and structure of chromosomes;
- c. *molecular genetic tests means* tests to determine the molecular structure of nucleic acids (DNA and RNA) and the immediate gene product;
- d. *presymptomatic genetic tests means* 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 means* prenatal genetic testing and prenatal risk assessment;
- f. *prenatal genetic tests means* genetic tests during pregnancy to determine characteristics of the genetic material of the embryo or fetus;
- g. *prenatal risk assessment means* 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 means* genetic tests to determine a genetic risk for future offspring;
- i. *screening means* 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 medical devices means* ready-to-use products for the determination of characteristics of human genetic material;
- k. *DNA profile means* information specific to an individual which is obtained from the non-coding sequences of their DNA using molecular genetic techniques;
- l. *genetic data means* information about the genetic material of a person that is obtained from a genetic test, including their DNA profile;
- m. *sample means* biological material collected for a genetic test;

- n. *person concerned* means 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 of Genetic Testing

Article 4 Non-discrimination

No one may be discriminated against on grounds of his or her genetic material.

Article 5 Consent

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

² If the person concerned is incapable of judgement, that person's legal representative shall provide consent on his or her behalf. In the medical context the limitations of Article 10 paragraph 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 or her genetic status subject to Article 18 paragraph 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 Swiss Criminal 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;

⁴ SR 311.0

- 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 for Human Genetic Testing (Art. 35):

- 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 within the meaning of this Act may only be created 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 medical devices

¹ It is forbidden to supply genetic in vitro diagnostic medical 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 for 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 a 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 performed on a person incapable of judgement 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 person concerned is minimal.

Article 11 Prenatal tests

It is forbidden to perform 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 for 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 for the purpose of family planning may only be prescribed 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 prescribes a genetic test under the terms of paragraph 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 person concerned; 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 person concerned and his or her family.

³ The person concerned or, if he or she is not capable of judgement, his or her 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 must be adapted 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 provides information about the risk of the embryo or fetus having a genetic anomaly, and before investigations of the embryo or fetus using imaging techniques, the pregnant 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 Act of 9 October 1981⁵ on Pregnancy Advisory Centres).

³ The 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 Right to self-determination

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

- a. whether to undergo a genetic or prenatal test and, where appropriate, a subsequent test;
- b. whether to know the result of the test; and
- c. what conclusions he or she wishes to draw from the test result.

² The doctor must immediately inform the person concerned of the test result if there is 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 for the purpose of family planning must be obtained in writing, with the exception of screening tests.

⁴ If the person concerned is incapable of judgement, his or her 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 or she is incapable of judgement, to his or her legal representative.

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

³ If consent is denied, the doctor may apply to the competent cantonal authority as stipulated in Article 321 number 2 of the Swiss Criminal Code⁶ to be released from his or her 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 for Human Genetic Testing.

Article 20 Further use of biological material

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

⁵ SR 857.5

⁶ SR 311.0

² Genetic tests for research purposes may be performed on biological material obtained for other purposes provided that the anonymity of the person concerned is ensured and that the person concerned or, if he or she is incapable of judgement, his or her legal representative, has been informed of his or her rights and has not expressly forbidden the use of the material for research purposes.

³ Otherwise the special legal provisions governing research apply.

Chapter 4: Genetic Testing in the context of Employment

Article 21 Principle

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

- a. require presymptomatic genetic tests 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 performed with the intention of detecting personal characteristics of the employee which do not relate to his or her 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 prescribe a presymptomatic genetic test if the following conditions are met:

- a. Suva 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 or her 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 Act of 20 March 1981⁷ on Accident Insurance 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 of the person carrying out the job and occupational disease, danger of environmental contamination or a risk of accident or health hazards to third parties.
- d. The Expert Commission for Human Genetic Testing has confirmed the causal relationship and has deemed the type of test to be reliable in identifying the relevant genetic predisposition.
- e. The person concerned has given his or her written consent to the test.

⁷ SR 832.20

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 Suva, 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 Employment Act of 13 March 1964⁸ or the Federal Act of 20 March 1981⁹ on Accident Insurance 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

Insurance providers may not require either presymptomatic or prenatal genetic tests prior to providing insurance.

Article 27 Prohibition of further enquiries

¹ Insurance providers may neither require the disclosure of, nor utilize, results of prior 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 Act of 6 October 2000¹⁰ on General Aspects of Social Insurance Law;
- 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;

⁸ SR 822.11

⁹ SR 832.20

¹⁰ SR 830.1

- 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 relevant information.

Article 28 Permissible further enquiries about results of prior presymptomatic genetic tests

¹ Before a private insurance policy not covered by Article 27 is taken out, insurance providers may only require the applicant to disclose the results of prior presymptomatic genetic tests to the designated doctor 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.

Chapter 6: Genetic testing in the context of Liability

Article 29 Prohibition of presymptomatic genetic testing

¹ Performing presymptomatic genetic tests 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 prior presymptomatic or prenatal genetic tests or tests for family planning purposes, for the purpose of calculating claims or determining compensation, is forbidden.

Article 30 Detection of diseases

Genetic tests to diagnose a disease 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 profiling to determine Filiation or Identity

Article 31 Principle

¹ When creating DNA profiles to determine filiation or for identification purposes it is not permitted to seek 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 or her 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 laboratory must retain the samples obtained in the course of the proceedings. The court which ordered the test ensures that the samples are destroyed immediately after the implementation of the final judgment, unless a person concerned has requested in writing that his or her samples be retained for a further 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 persons 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 administrative proceedings

¹ Outside the context of administrative proceedings, DNA profiling to determine filiation may be performed only with the written consent of the persons concerned; a child incapable of judgement and whose filiation with a certain person 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 persons 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 or she is incapable of judgement, his or her legal representative, shall decide whether his or her sample shall be retained or destroyed.

⁴ Prenatal DNA profiling to establish paternity may not be prescribed by a doctor unless the pregnant 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 for 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 (Art. 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. At the request of the competent federal authority, to comment on requests for authorisation and to participate in inspections (Art. 8 para. 1 and 2);
- c. To make recommendations on whether certain genetic in vitro diagnostic medical devices should be exempted from the prohibition stipulated in Article 9 paragraph 1;
- d. To advise on screening programmes (Art. 12);
- e. Where necessary, to make recommendations on post-graduate training as stipulated in Article 13 paragraph 2;
- f. To make recommendations on genetic counselling (Art. 14 and 15) and information relating to prenatal risk assessment (Art. 16);
- g. To advise, on request from the competent cantonal authority, on applications for release from the duty of professional secrecy (Art. 19 para. 3);
- h. To provide confirmations as stipulated in Article 22 letter 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: Criminal Provisions

Article 36 Genetic tests performed without consent

Any person who wilfully prescribes or performs a genetic test without obtaining the consent of the person being tested, as required by this Act, shall be liable to a custodial sentence not exceeding three years or to a monetary penalty.¹²

Article 37 Genetic testing without authorisation

Any person who wilfully performs a genetic test on a third party without the authorisation stipulated in Article 8 shall be liable to a fine.¹³

Article 38 Supply of genetic in vitro diagnostic medical devices

¹ Any person who, in contravention of Article 9 paragraph 1, wilfully supplies genetic in vitro diagnostic medical devices to individuals for a purpose which cannot be considered part of those individuals' professional or commercial activities shall be liable to a fine.¹⁴

² If the act is committed for commercial gain, the penalty shall be a custodial sentence not exceeding three years or to a monetary penalty.¹⁵

Article 39 Abuse in the context of employment

Any person who, in contravention of Article 21 and in the context of employment, wilfully:

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

shall be liable to a custodial sentence not exceeding three years or to a monetary penalty.¹⁶

Article 40 Abuse in the context of insurance

Any person who, in the context of insurance, wilfully:

¹² Amended in accordance with Art. 333 of the Swiss Criminal Code (SR 311.0) in its version in the Federal Act of 13 Dec. 2002, in force since 1 Jan. 2007 (AS **2006** 3459).

¹³ Amended in accordance with Art. 333 of the Swiss Criminal Code (SR 311.0) in its version in the Federal Act of 13 Dec. 2002, in force since 1 Jan. 2007 (AS **2006** 3459).

¹⁴ Amended in accordance with Art. 333 of the Swiss Criminal Code (SR 311.0) in its version in the Federal Act of 13 Dec. 2002, in force since 1 Jan. 2007 (AS **2006** 3459).

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¹⁶ Amended in accordance with Art. 333 of the Swiss Criminal Code (SR 311.0) in its version in the Federal Act of 13 Dec. 2002, in force since 1 Jan. 2007 (AS **2006** 3459).

- a. in contravention of Article 26, requires presymptomatic or prenatal genetic tests to be performed; or
- b. in contravention of Article 27, requires the disclosure of the results of prior presymptomatic or prenatal genetic tests or tests for family planning purposes, or asks about these in the context of a medical risk assessment, or makes use of such results.

shall be liable to a custodial sentence not exceeding three years or to a monetary penalty.¹⁷

Article 41 Competent authority and administrative criminal law

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

² Articles 6 and 7 (offences committed within a company) and 15 (forgery, fraudulent obtention of a false certificate) of the Federal Act of 22 March 1974¹⁸ on Administrative Criminal Law apply.

Chapter 10: Final Provisions

Article 42 Authorisation to perform genetic testing

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

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

Article 43 Screening

Screening programmes which have already been implemented by the time this Act comes into force do not require authorisation.

Article 44 Referendum and commencement

¹ This Act is subject to optional referendum.

² The Federal Council shall determine its commencement date.

Commencement date: 1 April 2007¹⁹

¹⁷ Amended in accordance with Art. 333 of the Swiss Criminal Code (SR 311.0) in its version in the Federal Act of 13 Dec. 2002, in force since 1 Jan. 2007 (AS 2006 3459).

¹⁸ SR 313.0

¹⁹ Federal Council Decree of 14 February 2007 (AS 2007 649)