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## **Federal Act on Human Genetic Testing (HGTA)**

of 8 October 2004 (Status as of 1 January 2014)

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*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 Constitution<sup>1</sup>,

and having considered the Dispatch of the Federal Council dated 11 September 2002<sup>2</sup>,

*decrees:*

### **Chapter 1: Scope, Purpose and Definitions**

#### **Art. 1**          Scope

<sup>1</sup> 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.

<sup>2</sup> 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 2003<sup>3</sup> applies to the use of DNA profiles in criminal proceedings and for the purpose of identifying unknown or missing persons.

<sup>3</sup> This Act does not apply to genetic testing performed for research purposes.<sup>4</sup>

AS 2007 635

<sup>1</sup> SR 101

<sup>2</sup> BBl 2002 7361

<sup>3</sup> SR 363

<sup>4</sup> Amended by Annex No 3 of the Human Research Act of 30 Sept. 2011, in force since 1 Jan. 2014 (AS 2013 3215; BBl 2009 8045).

**Art. 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.

**Art. 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 foetus;
- g. *prenatal risk assessment means* laboratory tests which provide information about the risk of the embryo or foetus having a genetic anomaly, and investigations of the embryo or foetus 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

### Art. 4 Non-discrimination

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

### Art. 5 Consent

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> Consent may be withdrawn at any time.

### Art. 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.

### Art. 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 Code<sup>5</sup>; and
- b. federal and cantonal data protection regulations.

### Art. 8 Authorisation to perform genetic testing

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

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

#### **Art. 9** Genetic in vitro diagnostic medical devices

<sup>1</sup> 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.

<sup>2</sup> 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**

#### **Art. 10** Genetic testing of individuals

<sup>1</sup> 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.

<sup>2</sup> 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.

#### **Art. 11** Prenatal tests

It is forbidden to perform prenatal tests whose purpose is:

- a. to determine characteristics of the embryo or foetus which do not directly impair its health; or

- b. to determine the sex of the embryo or foetus for a purpose other than diagnostic.

#### **Art. 12** Screening

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

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

#### **Art. 13** Right to prescribe genetic tests

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

<sup>2</sup> 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.

<sup>3</sup> The doctor who prescribes a genetic test under the terms of paragraph 2 ensures that the person concerned receives genetic counselling.

#### **Art. 14** Genetic counselling in general

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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;