Dokument	**LSR 2023 S. 31**
Autor	**Andreas Wildi, Lucina Herzog, Simon Mazidi**
Titel	**The Revised Law on Human Genetic Testing**
Seiten	**31-38**
Publikation	**Life Science Recht - Law journal for pharma, biotech, and medtech**
Herausgeber	**Philippe Fuchs, Claudio Helmle, Andri Hess, Michael Isler, Valérie Junod, Michael Noth, Janine Reudt-Demont, Barbara Schroeder de Castro Lopes, Martin Wilming**
Frühere Herausgeber	**Andreas Schöllhorn**
ISSN	**0031-9688**
Verlag	**Stämpfli Verlag AG**

The Revised Law on Human Genetic Testing

Catching-up or Leading the Way?

Andreas Wildi Dr. med. et lic. iur., Attorney at Law, Walder Wyss AG, Zurich/Berne; Lecturer at University of Lucerne

Lucina Herzog LL.M., Attorney at Law (Bar Association Frankfurt a.M.), Walder Wyss AG, Zurich

Simon Mazidi MLaw, Trainee Lawyer, Walder Wyss AG, Zurich; Lecturer at University of Fribourg

Keywords: DNA, Genetic Testing, HGTA-Revision, DTC-GT, Lifestyle Tests

I. Introduction

Today, genetic testing can be carried out easily and cheaply. While raising delicate medical, ethical, psychological and social questions, genetic testing has become widely available to the general public. Interested individuals can order so-called “direct-to-consumer genetic tests” (DTC-GT) online from numerous, oftentimes non-Swiss based suppliers for both medical and non-medical purposes. In particular DNA testing for lifestyle purposes has seen a lucrative rise and promises help and optimization in the areas of ancestry, health, beauty and dating.

The Federal Act on Human Genetic Testing (HGTA) in its original version came into force in 2007 and naturally did not reflect the technological progress made since. Parliament has therefore instructed the Federal Council to review the Act and close legal loopholes. Although the revision was largely prompted by the recent availability of DTC-GT, the HGTA and implementing legislation were revised comprehensively and cover all key problem areas identified by the Expert Commission for Genetic Testing on Humans.

On June 15, 2018, Parliament passed the revised HGTA, which was unanimously approved by the National Council and Council of States. Following the adoption of the revised HGTA, the implementing legislation has been under revision as well. This concerns in particular the Ordinance on Human Genetic Testing (HGTO) and the Ordinance on DNA Profiling in Civil and Administrative Matters (DCAO). The revised HGTA and its ordinances entered into force on December 1, 2022.

II. Key Changes Under the Revised Act

A. Scope of Application and General Principles

The Federal Act on Human Genetic Testing is characterized by its ambition to regulate genetic testing almost comprehensively. This clearly distinguishes it from the previous Federal Act, which was primarily limited to regulating genetic tests in the medical field.[1] The latter determined under which conditions genetic testing could be conducted in the medical field and the extent to which DNA profiles could be created for the purpose of determining the filiation or identity of an individual. The two core elements of the former Federal Act were, first, that genetic tests could only be ordered by physicians and, second, that only laboratories with an authorization from the Federal Office of Public Health (FOPH) could perform these tests. Even though the former Federal Act had

only been in force since April 1, 2007, rapid scientific and technological progress (next generation sequencing, microarray etc.) and developments in the field of human genetic testing had already given rise to a fundamental revision of the Act.[2] In particular, numerous technical possibilities that have emerged in the meantime and have considerably increased the quality of genetic analyses have made it possible to perform human genetic testing at lower costs and, above all, not only for medical purposes (lifestyle examinations).[3] In that regard, one can find a broad offer regarding genetic testing, such as for athletic predisposition, nutrition, and genealogy – which are aimed directly at individuals and are usually offered in a commercial manner across borders via the Internet.[4]

The lawfulness of such genetic testing outside the medical field was controversial under the former Federal Act.[5] As the revised HGTA now explicitly addresses and regulates these types of activities, it has closed an important gap by laying down legal requirements and providing legal certainty.[6] In doing so, it does not proceed on the basis of general prohibitions,[7] but rather takes a risk-based approach: By defining general legal requirements, it aims to prevent misuse in the performance of genetic tests. These general principles ensure the correct handling of genetic data, the quality of the tests performed as well as the interpretation of the results.[8] The adaptability and flexibility of the regulatory approach taken also allows future technological developments to be considered.

The revised HGTA has now a much larger scope of application. Next to regulating medical genetic testing, it also encompasses genetic testing outside the medical field.[9] With regards to the latter, the HGTA draws a distinction between, on the one hand, genetic testing that relates to properties worthy of protection for their potential significant impact on a person's personality and well-being and, on the other hand, genetic testing that involves properties having a comparatively insignificant impact on a person's lifestyle or behavior. The only genetic tests not covered by the revised HGTA are those already adequately covered by other regulations. This applies to reproductive medicine, human research and DNA profiles in criminal proceedings.[10]

---

1 Dispatch on Human Genetic Testing, BBl 2017 5597 et seqq., 5607.

2 Dispatch HGT (n 1), 5606 et seq.; Schott Markus/Mayoraz Jean-François, Totalrevision des Bundesgesetzes über genetische Untersuchungen beim Menschen, LSR 2018, 268.

3 Dispatch HGT (n 1), 5606.

4 Schott/Mayoraz (n 2), 267 and 269.

5 Schott/Mayoraz (n 2), 269. Cf. also Dispatch HGT (n 1), 5607 et seq., for further areas in which legal clarification was needed.

6 Dispatch HGT (n 1), 5616; Gächter Thomas/Koller Petra, Entwicklungen im Gesundheitsrecht – Rechtsetzung, in: Ueli Kieser/Agnes Leu (eds.), 5. St. Galler Gesundheits- und Pflegerechtstagung, Referate der Tagung vom 31. August 2017, Zurich 2018, 16.

7 Cf. Schott/Mayoraz (n 2), 270.

8 Cf. Art. 1 para. 1 let. b and let. c HGTA.

9 Boller Marcel, Revision of the Regulation on Genetic Testing, LSR 2020, 177.

10 Art. 2 para. 3 and para. 4 HGTA; Dispatch HGT (n 1), 5621 et seq. Cf. Federal Act on Medically Assisted Reproduction, Federal Act on Research involving Human Beings and Federal Act on the Use of DNA Profiles in Criminal Proceedings and for Identifying Unidentified or Missing Persons.

Whilst the three categories introduced in the HGTA are each subject to different regulations and legal requirements, there are provisions that apply to all genetic tests, whether prescribed inside or outside the medical field. These general provisions are mostly related to the legal protection of personality.[11] In this regard, genetic testing may not be performed unless the individual concerned has been provided with adequate information about the testing and has given his or her voluntary consent.[12] Furthermore, every person has the right to receive information resulting from a genetic examination but also to refuse information about his or her genetic status.[13] Finally, requirements are laid down in case samples and genetic data are to be used for other purposes. For that reason, the processing of genetic data is subject not only to federal and cantonal data protection regulations, but also to specific requirements for the protection of samples and genetic data, such as the safeguarding and retention of genetic data.[14]

B. Key Regulatory Distinction

1. Medical Genetic Testing

Medical genetic testing can be characterized by the fact that it is subject to a clinical question, it takes place in a medical context (doctor's office or hospital), and it is primarily intended to detect, prevent, and treat diseases and medical conditions.[15] The HGTA specifies that medical genetic testing includes diagnostic, presymptomatic and prenatal genetic examinations, prenatal risk assessments, family planning examinations and other genetic examinations performed for medical purposes, in particular to clarify the effects of a possible therapy.[16]

Compared to the former Federal Act, the regulation of genetic tests in the medical field is subject to *only minor changes.*[17] As a matter of principle, the prescription of such tests is reserved for physicians and

the performance is only permitted in approved laboratories.[18] This ensures that the instruction of a genetic examination is based on a professional opinion and is part of a medical treatment relationship. The personal exchange between the physician and the person concerned allows furthermore to ensure adequate information and consultation as a precondition for a self-determined and informed decision by the person concerned.[19] Similarly, the sample collection in the doctor's office or in the hospital and the transfer of the sample to an approved laboratory take place in controlled processes, which means that the risk of improper handling of samples and data can be effectively countered.[20]

Generally, genetic tests may only be prescribed by physicians who are authorized to practice their profession independently and who have a continuous medical education diploma in the specialized field to which the testing in question is related or who have a special qualification in the field of human genetics.[21] Therefore, for example, genetic testing in the area of metabolic diseases can be prescribed by physicians qualified in endocrinology, just as in the area of cardiovascular diseases a cardiologist may arrange for testing.[22]

---

11 Cf. FOPH, Questions and Answers, Human genetic testing: An overview of the new rules, 1 December 2022, < https://www.bag.admin.ch/dam/bag/de/dokumente/biomed/genetischeuntersuchung/aktuelle-rechtsetzungsprojekte/brb-ikt/fragen-antworten-ueberblick-neue-regeln.pdf.download.pdf/221201_fragen-antworten-ueberblick_de.pdf > (accessed 18 January 2023), 3 et seq.

12 Art. 5 and Art. 6 HGTA.

13 Art. 7 and Art. 8 HGTA.

14 Art. 10–12 HGTA.

15 Dispatch HGT (n 1), 5616.

16 Art. 19 HGTA.

17 Schott/Mayoraz (n 2), 270.

18 Art. 20 para. 1 and Art. 28 para. 1 HGTA; Gächter/Koller (n 6), 17 et seq.

19 Cf. Art. 5 HGTA.

20 Dispatch HGT (n 1), 5617.

21 Art. 20 para. 1 let. a and let. b HGTA; FOPH, Questions and Answers, Revision of the Ordinance on Human Genetic Testing (HGTO), 1 December 2022, < https://www.bag.admin.ch/dam/bag/de/dokumente/biomed/genetischeuntersuchung/aktuelle-rechtsetzungsprojekte/brb-ikt/fragen-antworten-revision-gumv.pdf.download.pdf/221201_fragen-antworten-revision-gumv-de.pdf > (accessed 18 January 2023), 2.

22 Cf. FOPH, Questions and Answers HGTO (n 21), 2.

The revised HGTA gives the Federal Council leeway by allowing it to increase or relax the professional requirements for prescribing a genetic test in the medical field after having consulted the Federal Commission for Human Genetic Testing. For genetic examinations that require increased information, counseling, or interpretation of the results, the Federal Council may restrict the prescription of medical genetic testing to physicians with certain qualifications. Conversely, the Federal Council may also allow other health specialists to order certain genetic examinations in the medical field such as pharmacists, nutritionists, or psychologists.[23] In this way, the Federal Council can respond in a flexible manner to new medical and technological changes.[24]

The Federal Council made use of its authority when implementing the HGTA and designated health professionals in the HGTO who, in addition to specialized physicians, are allowed to prescribe genetic tests in the medical field.[25] Pharmacogenetic tests may, for instance, be prescribed by physicians without corresponding specializations and by dentists, pharmacists, or chiropractors, who are authorized to practice their profession independently.[26] The underlying assumption here is that pharmacogenetic tests require a lower level of information, consultation, and interpretation than other genetic tests in the medical field.

To ensure quality, the *laboratories* entrusted with these tests are, as under the former Federal Act, subject to authorization by the FOPH and its supervision.[27] As a new requirement, these laboratories must also have accreditation according to international quality standards.[28] Physicians who have prescribed a genetic test or domestic laboratories may, under certain conditions, transfer the examination of a genetic test in whole or in part to a laboratory *abroad.* Among other things, the individual concerned must be informed prior to the transfer abroad and consent in writing. The laboratory abroad must have a quality management system in place in accordance with the relevant standards and, if the examination is carried out in a jurisdiction where the legislation does not provide for adequate data protection, the sample must be pseudonymized and the individual concerned must be informed thereof.[29] This also applies to genetic testing outside the medical field when the examination is related to personality traits worthy of protection.[30]

2. Genetic Testing Outside the Medical Field

Genetic data may be of a sensitive nature even if it does not contain relevant medical information. In this context, special protection against misuse or abuse is necessary. Against this background, the HGTA divides genetic examinations outside the medical field into two subcategories, which are subject to different legal requirements and levels of regulation.

a) Genetic Testing of Personal Properties of Sensitive Nature

Genetic tests outside the medical field that relate to sensitive personality traits and therefore require special protection are those that result in information that may have a *significant impact on the personality* of the individual concerned. This includes ex-

LSR 2023 S. 31, 34

aminations which aim to clarify the metabolic type to optimize weight by suitable nutrition or sporting activity, or genetic testing for suitability for certain disciplines of sport. In addition, genetic tests on *personality traits* such as character or behavior (e.g. intelligence or aggression potential) or *origin analyses* (e.g. genealogical research using genetic methods) fall into this subcategory.[31] They differ from medical genetic testing as they do not follow any medical purpose and therefore do not supply any information about predisposition to disease or risk of disease of the individual concerned. Yet they require special protection because they

---

23 Art. 20 para. 2 and para. 3 HGTA; Dispatch HGT (n 1), 5685 et seq.; Schott/Mayoraz (n 2), 270.

24 Dispatch HGT (n 1), 5686.

25 In the HGTO the Federal Council did, however, not increase the professional requirements for prescribing a genetic test in certain medical fields. Cf. Boller (n 9), 178 et seq.

26 Cf. Art. 5–8 HGTO. They must fulfil, however, the criteria set out in Art. 5 para. 2 HGTO. Cf. Boller (n 9), 179 et seq.

27 Art. 28 para. 1 HGTA and Art. 14 et seqq. HGTO; Dispatch HGT (n 1), 5617.

28 Art. 28 para. 3 and para. 4 let. a HGTA and Art. 9 HGTO; FOPH, Questions and Answers HGTO (n 21), 5; Boller (n 9), 181.

29 Art. 29 HGTA; Art. 3 para. 4, Art. 28 and Art. 58 HGTO; FOPH, Questions and Answers HGTO (n 21), 5; Schott/Mayoraz (n 2), 270.

30 Art. 36 HGTA.

31 Dispatch HGT (n 1), 5617 et seq.; FOPH Questions and Answers HGTO (n 21), 4; cf. Art. 31 para. 1 let. a to let. c HGTA; Boller (n 9), 180; Gächter/Koller (n 6), 16; Schott/Mayoraz (n 2), 271.

contain information that reveals physiological characteristics or physical conditions that may either affect lifestyle, or carry an increased risk of discrimination, or allow for the exclusion of paternity.[32]

These genetic examinations need additional regulation as they generate comparatively sensitive data that must be protected from misuse. Since they are not conducted for medical purposes, they may be performed outside the doctor's office or hospital.[33] They are, however, subject to an increased level of regulation. One notable manifestation of this increased level of regulation is that these genetic tests must be prescribed by *health professionals.*[34] The Federal Council is entrusted with defining the specific categories of health professionals to conduct these tests.[35] In doing so, the Federal Council designated as health professionals, in addition to physicians, also pharmacists, psychologists and chemists.[36] Moreover, limited to the clarification of physiological properties, nutritionists, physiotherapists, chiropractors, and osteopaths may also prescribe genetic tests. To prevent misuse, the sample collection, e.g. saliva or cheek swab, must take place in the presence of the health professional.[37]

Like medical genetic testing, *laboratories* that carry out examinations for the purpose of clarifying personality traits of sensitive nature outside the medical field are subject to authorization and supervision. While a quality management system in accordance with international standards is required, the accreditation by the Swiss Accreditation Service (SAS) is not.[38]

The limitation to healthcare professionals and approved laboratories is intended to prevent particularly sensitive personality traits from being examined and misused by third parties without being noticed.[39]

b) Genetic Testing for Other Properties (Direct-to-Consumer Genetic Testing)

The remaining non-medical genetic tests that are neither related to personality traits worthy of protection nor performed for DNA profiling, are subject to a lower level of regulation.[40] These tests are not health related and either provide information about already known properties on external appearance or are considered as carrying a *relatively low risk of misuse.*[41] Such tests may relate to physical appearance, such as height, eye color, or hair color, or they may provide information about the sense of taste, earwax consistency, or choice of partner.[42] It is permissible to deliver such tests directly to consumers, notably via the Internet, which gave them the abbreviation "direct-to-consumer genetic testing (DTC-GT)". The individual concerned may take the sample at his or her own place. In contrast to medical genetic testing and testing associated with personality traits worthy of protection outside of the medical field, no involvement of health professionals is needed and laboratories performing DTC-GTs are not subject to authorization.[43] Because genetic testing may be performed on individuals lacking the capacity to consent only when necessary to protect their health,[44] DTC-GT cannot be supplied to or used on young children and other individuals who are unable to consent.[45]

Forced to deal with new Internet offerings, the revised HGTA takes a step forward in this area by generally allowing DTC-GT. At the same time, it substantially limits the scope of application of DTC-GT to examinations that are deemed to only have low potential for misuse. Since the definition of genetic tests relating to personality traits worthy of protection is formulated very broadly, only a neglectable area of use remains for genetic testing for other properties. DTC-GT without any involvement of health professionals will therefore remain the exception when looking at Lifestyle DNA tests at large (see below under sec. III.A. for a more detailed delimitation of test categories and examples).

---

32 Dispatch HGT (n 1), 5617 et seq.

33 Gächter/Koller (n 6), 17.

34 Art. 34 HGTA.

35 Art. 34 para. 4 HGTA.

36 Art. 40 HGTO.

37 Art. 34 para. 3 HGTA; FOPH, Questions and Answers, Human genetic testing (n 11), 5.

38 Art. 35 HGTA; Dispatch HGT (n 1), 5618; FOPH, Questions and Answers HGTO (n 21), 5; Boller (n 9), 181 et seq.

39 Dispatch HGT (n 1), 5620.

40 Art. 31 para. 2 HGTA.

41 FOPH, Questions and Answers HGTO (n 21), 4.

42 Dispatch HGT (n 1), 5618; FOPH, Questions and Answers HGTO (n 21), 4; Gächter/Koller (n 6), 17; Schott/Mayoraz (n 2), 272.

43 FOPH, Questions and Answers, Human genetic testing (n 11), 5. Cf. Tavel Coralie, Informationspflicht des Anbieters von direct-to-consumer Gentests nach dem Vorentwurf zum GUMG, Jusletter 30. Janaury 2017, n 8 et seqq.

44 Art. 16 para. 1 HGTA. Cf. for the exceptions para. 2 of the provision.

45 FOPH, Questions and Answers, Human genetic testing (n 11), 6.

C. Other Areas of Regulatory Groundwork

In addition to the scope of application, several key areas have undergone significant changes with the HGTA revision. For this purpose, we will briefly discuss (1) the handling of surplus information from genetic examinations, (2) prenatal genetic testing in connection with determining the sex of the unborn

child, (3) requirements for advertising to the public and (4) the performance of DNA profiling, particularly on deceased persons.

1. Surplus Information

The possibility of analyzing the entire genome or large parts of it in a short period of time frequently generates genetic data that is not needed for the purpose of the genetic examination in question.[46] Against this backdrop, the HGTA provides as one of its general principles that an excess of information must be avoided as far as possible.[47]

Regarding medical genetic testing, the individual concerned must be adequately informed by the physician before the examination takes place that surplus information could be generated.[48] If surplus information arises, the individual concerned decides to what extent he or she wishes to be informed about it.[49] If the genetic test was prescribed by a health professional other than a physician, surplus information must not be shared.[50]

By contrast, it is – in any case – prohibited to communicate surplus information resulting from genetic examinations outside the medical field and DNA profiles. The HGTA explicitly states that the individual concerned may only be informed about those characteristics that correspond to the purpose of the examination.[51]

2. Prenatal Testing

For some years now, methods have been available to detect anomalies in the unborn child at an early stage of pregnancy without posing a risk to the mother or child.[52] In this regard, non-invasive prenatal tests are preferred, in which small DNA fragments circulating in the blood of a pregnant woman are analyzed. It should, however, be noted that the HGTA not only applies to prenatal genetic examinations but also to other forms of prenatal risk assessments.[53] The potential for early detection of health concerns associated with these methods raises social and ethical issues.[54] As has been the case under the former Federal Act, it is forbidden to perform prenatal tests with the purpose of *determining characteristics of the embryo* which do not directly impair its health.[55] More specifically, the HGTA provides for only three constellations in which prenatal testing is permitted: First, prenatal testing is allowed to detect characteristics that directly affect the health of the embryo. Second, it is permissible to check blood groups or blood characteristics to prevent complications resulting from a potential incompatibility between mother and fetus or to treat the consequences of such complications. Finally, prenatal testing is allowed when necessary to clarify whether the cord blood of the embryo or the fetus is suitable for transfer to a parent or a sibling due to its tissue characteristics considering a possible postnatal blood stem cell transplantation.[56]

---

46 Dispatch HGT (n 1), 5622; Schott/Mayoraz (n 2), 273.

47 Art. 9 HGTA.

48 Art. 6 let. d HGTA.

49 Art. 27 para. 1 HGTA; Gächter/Koller (n 6), 19.

50 FOPH, Questions and Answers, Human genetic testing (n 11), 4.

51 Art. 33 HGTA; Dispatch HGT (n 1), 5623; Gächter/Koller (n 6), 19.

52 Cf. FOPH, Questions and Answers, Human genetic testing (n 11), 2 et seq.

53 Dispatch HGT (n 1), 5679.

54 Cf. for a comprehensive presentation and discussion of the topic Brauer Susanne/Strub Jean-Daniel/Bleisch Barbara/Bolliger Christian/Büchler Andrea et al. (eds.), Wissen können, dürfen, wollen?, Genetische Untersuchungen während der Schwangerschaft, Zurich 2016.

55 Schott/Mayoraz (n 2), 272.

56 Art. 17 para. 1 HGTA.

Thanks to technological progress, it has become increasingly easy to *determine the sex* of the unborn child at an early stage, oftentimes even incidentally. Non-invasive prenatal tests in the context of chromosome analysis are one way to provide such early information. Others would be prenatal examinations such as ultrasound. Upon revision, the HGTA now specifies that the sex of the unborn child may be determined only if it is for the purpose of diagnosing a medical condition.[57] In any other case the physician is not allowed to communicate the sex of the embryo or fetus to the pregnant woman before the end of the twelfth week starting on the date of the woman's last menstrual period. According to the legislator's intention, this is meant to prevent undesirable gender selection.[58] The timing chosen in the HGTA is based on the consideration that under Swiss federal law the termination of a pregnancy within the first twelve weeks is exempt from penalty.[59] After twelve weeks, a physician may still withhold the information when he or she is of the opinion that there might be a risk of terminating the pregnancy due to the sex of the unborn.[60] During the consultation procedure, which is part of the preparatory legislative process and gives the cantons, the political parties as well as the business community and other interest groups the opportunity to comment on the draft legislation, a majority of the participants expressed critical to negative opinions on this new provision relating to the determination of sex.[61] The main argument put forward relates to the woman's fundamental right of self-determination, in particular within the first twelve weeks in which abortion remains unpunished.

LSR 2023 S. 31, 36

3. Advertisement

Advertising to the public for medical genetic testing, prenatal genetic testing and genetic testing on persons lacking the capacity to consent is generally prohibited.[62] There is, however, one exception: Physicians and other health professionals who are authorized to prescribe medical genetic tests are, within a limited scope, allowed to engage in advertising.[63] Their advertising must be objective and meet the public need. Moreover, it must not be misleading or intrusive.[64]

For genetic examinations outside of the medical field and for the creation of DNA profiles such as paternity tests, advertising to the public is permitted under certain conditions. The advertisement must inform about the HGTA's requirements on prior information and communication of results and on the prohibition of genetic testing in the context of prenatal examinations and persons incapable of judgement.[65] Advertising to the public for genetic testing concerning personality traits worthy of protection must additionally refer to the need of a prescription by a health professional. Misleading information is prohibited.[66]

Advertising to professionals is not regulated by the HGTA. Here, general principles of unfair competition remain applicable whereby false or misleading statements are prohibited.[67]

---

57 Art. 17 para. 2 HGTA.

58 Dispatch HGT (n 1), 5723; Schott/Mayoraz (n 2), 272.

59 Art. 119 para. 2 Swiss Criminal Code.

60 Art. 17 para. 3 HGTA.

61 Federal Department of Home Affairs, Total revision of the Federal Act on Human Genetic Testing (HGTA), Report on the results of the consultation, February 2016, < https://www.fedlex.admin.ch/filestore/fedlex.data.admin.ch/eli/dl/proj/6013/53/cons_1/doc_7/de/pdf-a/fedlex-data-admin-ch-eli-dl-proj-6013-53-cons_1-doc_7-de-pdf-a.pdf > (accessed 18 January 2023), 6.

62 Art. 14 para 1 let. a HGTA. Cf. for a definition on the advertisement of genetic testing Art. 4 para. 3 HGTO.

63 Art. 14 para. 2 HGTA; Dispatch HGT (n 1), 5674 et seq.

64 Art. 4 para. 1 HGTO. The ordinance echoes the advertising restrictions already imposed on physicians and other health professionals by Art. 40 let. d Federal Act on Medical Professions and Art. 16 let. e Federal Act on Health Professions.

65 Art. 14 para. 3 HGTA and Art. 4 para. 2 HGTO. Cf. for DNA profiles the corresponding provision in Art. 47 para. 4 HGTA.

66 Art. 14 para. 3 HGTA and Art. 4 HGTO.

67 Art. 3 para. 1 let. b of the Federal Law on Unfair Competition.

4. DNA Profiles

The scope of application of DNA profiles under the HGTA is limited to investigations in civil or administrative proceedings and outside official proceedings. The latter is of particular importance for the investigation of family relationships between individuals, especially in the context of paternity tests.[68]

Compared to the former Federal Act, the revised HGTA only contains a few changes regarding DNA profiles for the purpose of determining the filiation or identity of an individual. As has been the case before, the identity of the person examined needs to be verified and DNA profiling may only be performed in principle with the written consent of the person concerned.[69] Additionally, DNA profiles may only be created by laboratories recognized by the Federal Department of Justice and Police.[70]

What has been newly added in the revised HGTA is the *DNA profiling of deceased persons.* If the person to whom the filiation is to be clarified is deceased, the person requesting the DNA profiling must put forward good reasons for such examination.[71] Good reasons may exist, for example, if there are reasonable doubts about the parentage established under civil law due to serious statements by family members or third parties or due to mismatching blood group images.[72] In addition, the next of kin (e.g. wife or husband, children) of the deceased person must consent to the examination.[73]

III. Implications and Unresolved Issues

A. Delimitation in Practice – Which Rules Apply?

With Lifestyle DNA tests on the rise, the new legislation may leave many wondering what it will mean for their (potential) conduct as physicians, health professionals or (new) businesses. The answer depends largely on which of the three categories presented above (sec. II.B.) their offer falls into, as different legal requirements apply. What is oftentimes considered a Lifestyle DNA test, promising to tailor the individual's diet, supplements and exercise for optimum weight, health and lifestyle, does not necessarily fall into the category of DTC-GT. In the contrary, most of these tests will be considered genetic testing of personal properties of sensitive nature, some even belong to the medical field. The delimitation might therefore pose difficulties in practice.

The legislator was aware of this and opted for a functional approach.[74] Assignment to the regulatory categories is based primarily on the *nature of properties* under examination. The first essential distinction is between genetic testing inside and outside of the medical field. If the examined property provides information about current or future possible health impairment or other relevant medically characteristics of the person concerned, this is considered a genetic examination in the medical field. Here, the following problem arises: The same examination, e.g. clarification of metabolic type, can be performed to optimize nutrition or to adjust a medically indicated therapy. If the examined property cannot be clearly assigned to one area, the *purpose of the examination* is decisive.[75] It is also possible that during the examination of a certain genetic trait, both medically irrelevant and medically relevant findings will be obtained (e.g. the gene for a possible metabolic type can also provide information about a possible lactose intolerance). If

this is the case, the examination can only be qualified as outside the medical field if solely the medically irrelevant information is conveyed to the individual concerned.[76]

The criteria determined by the legislator (nature of properties and purpose of examination) will find a sensible answer to most questions relating to the delimitation of medical and non-medical tests. To provide further guidance, the Federal Council provides a list of examples of properties that are considered medically relevant. These include food intolerances, addictive potential and behaviors, susceptibility to infections,

---

68 Dispatch HGT (n 1), 5715.

69 Art. 49 para. 1, Art. 50 para. 2 and Art. 51 para. 1 HGTA.

70 Art. 53 HGTA.

71 Art. 48 para. 1 let. a HGTA.

72 Dispatch HGT (n 1), 5717.

73 Art. 48 para. 1 let. b HGTA.

74 Dispatch HGT (n 1), 5618 et seq.

75 Dispatch HGT (n 1), 5619.

76 Dispatch HGT (n 1), 5619.

metabolic disorders, increased risk of sports injuries, diseases, allergies, or inflammation, mental disorders, developmental and intelligence disorders as well as personality and behavioral disorders.[77]

In case the genetic testing concerned is considered outside the medical field, the second question is whether the properties being investigated are considered particularly worthy of protection. Art. 31 para. 1 HGTA is (deliberately) worded openly in this regard. The examples provided by the Federal Council make it clear that the category of properties particularly worthy of protection is to be interpreted broadly. After all, they cover all physiological characteristics, knowledge of which can influence a person's lifestyle, particularly in the areas of dietary behavior, sporting activity and general well-being.[78] In addition, examinations of origin (e.g. genealogical research) are also assigned to this category.[79] What remains for DTC-GT are genetic tests on externally visible characteristics such as hair, eye color or height, those related to the sense of smell and taste, or – possibly of paramount commercial interest – choice of partner.[80] While this list of examples is not exhaustive, there does not seem much left to be qualified as genetic testing for other properties. If doubts remain about the allocation, it should be determined whether the properties in question are prone to discrimination or harm.

B. The New Role of Pharmacies

The new legislation allows pharmacists and other selected health professionals to dispense non-medical as well as selected medical tests. The exact scope of their competences changed in the course of the legislative process and was expanded once more. Initially, the Federal Council envisaged that pharmacists would only be allowed to arrange pharmacogenetic examinations that are (a) not related to a prescription pharmaceutical and (b) which provide results that can be easily interpreted and communicated. These restrictions met with criticism in the consultation process. It was commented that the restriction was cumbersome and unclear.[81] In particular, clarifications on non-prescription drugs are, so the criticism, generally not easy to interpret while the opposite is true for pharmacogenetic studies on individual prescription drugs.[82] Thus, one of the limitations would most likely be triggered, leaving little room for application. At the same time, the majority of the cantons as well as the associations of Swiss pharmacists, universities and mail-order pharmacies (pharmaSuisse, swissuniversities and VSVA) called for the expansion of dispensing authority for pharmacists.[83] In response to the criticism from stakeholders, the Federal Council abandoned the limitations and did not make pharmacogenetic testing dependent on the type of pharmaceutical. However, as a remnant of the original draft, pharmacists must consult with a medical professional if the pharmacogenetic testing is performed to clarify the effect of a prescription drug prescribed by said medical professional.[84]

The use of commercial pharmacogenetic tests is of particular benefit to people who wish to obtain information about the tolerability of drugs or the optimal dosage.[85] But above all, the revised HGTA opens up new and potentially lucrative business opportunities for pharmacies, especially with regard to non-medical genetic examinations.

C. Adequate Level of Protection for Non-Medical Genetic Tests

As stated above, most genetic tests in Switzerland must be prescribed by a health professional. This person provides qualified information and – if necessary – genetic counseling. He or she also guarantees that the sample comes from the person who is being tested and that consent is given. All these requirements serve

---

77 Art. 37 para. 2 and Art. 38 HGTO.

78 Art. 37 para. 1 HGTO.

79 Art. 39 HGTO.

80 Dispatch HGT (n 1), 5618; Art. 37 para. 3 HGTO.

81 Cf. Boller (n 9), 179.

82 Federal Department of Home Affairs, Total revision of the Federal Act on Human Genetic Testing (HGTO), Report on the results of the consultation, February 2022, < https://www.bag.admin.ch/dam/bag/de/dokumente/biomed/genetischeuntersuchung/aktuelle-rechtsetzungsprojekte/brb-ikt/gumv-vl-bericht.pdf.download.pdf/gumv-vl-bericht-de.pdf > (accessed 20 January 2023), 14.

83 Federal Department of Home Affairs (n 82), 14.

84 Art. 7 para. 2 HGTO.

85 Dispatch HGT (n 1), 5686.

to protect against abuse and misuse. Genetic tests may only be sold directly to consumers for clarification of comparatively harmless properties, such as earwax or hair structure.

Consumers should be aware that tests offered on the Internet may not fulfill such regulatory requirements. Many foreign companies offer a wide range of tests including those on disease predispositions or paternity tests. Enforcement of national regulations in this area is almost impossible. Consumers may order such tests for themselves without legal conse-

quences. Only those persons in Switzerland can be prosecuted who illegally commission genetic tests from foreign companies, e.g. to perform genetic testing to examine the intelligence of their child. In order to promote a responsible approach to genetic testing on the Internet, the FOPH informs the public about the possibilities and limits of genetic testing,[86] in particular about DTC-GT on the Internet.[87]

Another question arises as to whether the level of protection awarded by Swiss legislation for genetic tests outside the medical field is satisfactory. For DTC-GT, professional embedding and guidance is completely absent. For all other non-medical genetic tests, there exists not much guidance or consultation for the prescribing health professionals. It is advised that health professionals, who may offer non-medical genetic tests of personal properties of sensitive nature, undergo specific trainings. A solid knowledge of the basics and specifics of offered genetic testing (e.g. accuracy, statistical relevance of results, factual relevance of results, development of knowledge about detected genetic traits) seems inevitable before being able to advise customers professionally.

D. Data Privacy Challenges

Since the application of new technologies can generate large amounts of genetic data, the legislator paid special attention to protection against misuse in storage and use of samples and data for other purposes. Based on an expert opinion commissioned by the FOPH,[88] the HGTA provides several special provisions on data protection and privacy in the context of genetic testing on humans. Where there is no such special provision, general data protection laws apply. As of September 1, 2023, the revised Swiss Data Protection Act enters into force to further increase the level of protection. Notably, genetic data is to be included in the definition of data requiring special protection.[89]

The HGTA and its ordinances provide for special provisions, where it has been recommended by said expert opinion. Anyone processing samples and genetic data must protect them against unauthorized handling by taking appropriate technical and organizational measures.[90] All laboratories with a license must have a data security concept in place.[91]

No serious gaps in data protection can be identified, especially since general data protection laws apply on a subsidiary basis. Of particular interest and corresponding risk potential are data exports and use of genetic data for purposes other than arranged for. Both are regulated by the revised HGTA. Samples and genetic data must be pseudonymized if transferred to a country whose legislation does not ensure adequate protection and the person concerned must be informed.[92] Protection will be further ensured contractually as is already standard practice under general data protection laws. Moreover, samples and genetic data may only be used for another purpose if the person concerned has freely and explicitly expressed consent.[93]

The only gap remains with respect to foreign providers of DTC-GT. Here, individuals may send their samples abroad to have their genetic data analyzed in other countries. In these cases, there is little regulatory leeway to prevent misuse. The legislator therefore rightly focuses on public education and the consumers' common sense and self-responsibility.

---

86 Cf. FOPH, Questions and Answers, Human genetic testing (n 11), 6.

87 Cf. FOPH, "Direct-to-consumer"-Gentests, < https://www.bag.admin.ch/bag/de/home/medizin-und-forschung/genetische-untersuchungen/info-gentests/dtc-gentests.html#-1849341026 > (accessed 20 January 2023).

88 Rosenthal David/Kessler Ilona, Datenschutzrechtliche Aspekte im Rahmen der Totalrevision des GUMG, 18 November 2015, Zurich.

89 Art. 5 let. c no. 3 of the revised Data Protection Act.

90 Art. 10 para. 1 HGTA and Art. 3 HGTO.

91 Art. 24 and Art. 54 HGTO.

92 Art. 10 para. 1 HGTA; Art. 3 HGTO.

93 Art. 12 para. 1 HGTA.

IV. Final Remarks

With the revised HGTA, the legislator has laid important regulatory groundwork for genetic testing in humans, both inside and outside the medical field. For one, the level of protection seems adequate in relation to the potential risks of the different categories of genetic tests. Although the delimitation of these categories can cause difficulties in practice, the examples offered by the ordinance together with the legislative reasoning provide essential tools to do so.

The revision was mainly destined to meet the current demands and challenges posed by the rapid technological advances of the past decade. But it does not stop here. By setting out basic principles and leaving the details to the Federal Council, the new regulatory framework offers enough flexibility to keep pace with technological developments and adjust where necessary. This will prevent the Act from having to be fully revised again in near future. All who are entitled to offer genetic testing outside DTC-GT, i.e. physicians and other health professionals, are advised to inform themselves diligently about the possibilities and impossibilities as well as the pros and cons of the genetic tests they intend to offer. This fast and broadly growing field is scientifically exciting, and it may be assumed that it will influence our lives and our behavior in ways not yet imaginable today: Positively if it is handled well, negatively and scaringly, if the interest of the tested person is not assessed very thoroughly and very caringly.