

Amendments to the Biotechnology Act – prohibition against genetic testing of children outside the health service

1 Introduction

The Ministry of Health and Care Services proposes amendments to the Biotechnology Act entailing the introduction of a prohibition against genetic testing of children outside the health service.

The proposed prohibition is based on the principle that predictive genetic testing of children is prohibited, but with the continuation of the current exemption if the testing can detect conditions that, through treatment, can prevent or reduce harm to the health of the child. Diagnostic testing of children under 16 years of age should only be permitted if it is requested by health personnel. In addition, the Ministry proposes to expand the definition of genetic testing under the Biotechnology Act, so that tests that are close to medical tests are also covered by the Act and the prohibition against testing of children. This applies to tests that are intended to provide information about a person's physical or mental characteristics or aptitude, personality traits, etc. The Ministry does not propose expanding the scope of the Biotechnology Act to also regulate paternity tests and other genealogy tests.

The prohibition shall apply to taking a biological sample of a person under the established age limit, ordering and carrying out DNA analysis of the sample. In addition, the Ministry proposes that the prohibition shall include the sale of genetic tests to children. The Ministry also proposes a prohibition against the use of genetic information derived from tests carried out contrary to the proposed prohibition against testing of children outside the health service, cf. the proposed amendments to Section 5-8. It is proposed that the prohibition shall be subject to criminal penalties for non-compliance in accordance with the provisions in Section 7-5 of the Biotechnology Act, but nevertheless so that parents and other private individuals are not exempt from criminal liability in the event of a contravention of the ban. However, in the event of a contravention of the prohibition in Section 5-7 and Section 5-8, third paragraph, it is proposed that parents and other private individuals shall not be punished by imprisonment. The Ministry is of the view that fines will be sufficient in such cases.

2 Background

In Petition Resolution 612 (2019–2020), the Storting asked the Government to submit a bill that ensures that genetic testing of children outside the health service is prohibited. To follow up on this resolution, the Ministry is submitting for consultation a proposal for the design of such a prohibition.

The Ministry proposes incorporating the prohibition into Section 5-7 of the Biotechnology Act. This provision currently regulates the conditions for being able to carry out predictive genetic testing of children under 16 years of age. The regulation of genetic testing of children under 16 years of age is then gathered in a single provision.

3 The Ministry's assessments and proposals

3.1 Purpose

According to the Ministry's assessment, a prohibition against genetic testing of children under 16 years of age outside the health service may help parents to a greater extent respect children's right to personal integrity. Genetic testing of children outside the health service challenges children's right not to be made aware of any disease risks. The tests can, among other things, reveal risks that do not offer a potential for prevention. Commercial self-tests also challenge privacy and the right to one's own health data. It is the child themselves, when sufficiently mature, who must be allowed to decide whether or not they want such information.

3.2 What acts are covered by the ban?

The Ministry is of the view that the acts to be covered by the prohibition should be to order a genetic test of a person under the established age limit, and to carry out DNA analysis of the sample. This also includes ordering or carrying out a reanalysis of a sequence, e.g., from a previous diagnostic test. Who it is that takes the biological sample is, in principle, not important. The prohibition will cover both samples ordered by health personnel and self-tests taken by private individuals. Ordering a test will cover both health personnel who request an analysis and private individuals who purchase self-tests and send biological material for analysis. Enterprises that analyse the samples will also be covered by such a description of the offence. Enterprises established in Norway will not be able to offer tests aimed at children or carry out analyses if it is stated that the person being tested is below the age limit.

However, acts performed by health personnel will in many cases be exempt. It is proposed to make a delimitation of the prohibition from diagnostic tests ordered by health personnel as well as predictive genetic tests to the extent these meet the conditions in the current Section 5-7 (the test can detect conditions that, through treatment, can prevent or reduce harm to the health of the child).

In principle, the prohibition does not relate to the sale of the tests. Firstly, it will be difficult to enforce such a prohibition against foreign companies that sell tests online. The companies that offer or sell tests in Norway will also have an indirect responsibility for assessing whether the tests are to be used by adults or children, as it will still be permitted to sell self-tests to adults. Prohibiting the "purchase" of the tests entails a responsibility on the part of the enterprises to assess whether the tests are being purchased to test a child. However, the Ministry proposes a prohibition against selling specific genetic tests, including self-tests (tests sold directly to the consumer), to children under the established age limit. There is a responsibility on the part of enterprises that sell such tests or examinations to know the age of the person purchasing the test, and this responsibility is similar to the prohibition against selling alcohol to persons under 18 or 20 years of age, respectively, cf. Section 1-5 of the Alcohol Act. For sales via the internet, it will be sufficient that the enterprises inform of the age limit for the purchase of the tests and ask the buyer to confirm that they are over 16 years of age.

The Ministry also proposes that the prohibition be subject to criminal penalties for non-compliance, see below. Article 96 of the Constitution of Norway therefore sets out requirements for the design of the ban. The principle of legality in criminal law requires a clear legal authority for imposing penalties. The punishability must follow from the law. Lack of support in the wording is not remedied by the fact that the offence is clearly punishable, and that the legislature undoubtedly sought to cover it. Therefore, the Ministry proposes to clarify the text of the Act so that all the alternative acts are explicitly stated.

3.3. What types of tests are covered by the ban?

The prohibition against testing of children outside the health service does not distinguish between tests for medical and non-medical purposes.

The scope of the Biotechnology Act for genetic testing is determined by the definition of genetic testing in Section 5-1. The definition currently covers medical tests with the purpose of diagnosing disease, cf. second paragraph, letter a. The definition further covers presymptomatic genetic testing, predictive genetic testing and genetic testing to determine whether or not a person is a carrier of hereditary disease that will only be expressed in later generations, cf. second paragraph, letter b. In addition, the definition covers laboratory genetic testing to determine sex. Laboratory genetic testing for identification purposes (paternity tests, etc.) is currently not covered by the definition in Section 5-1, cf. second paragraph, letter c. Therefore, such testing is also not covered by the scope of the Biotechnology Act.

The Ministry proposes to expand the definition of genetic testing to include testing that is close to medical testing, including testing with the purpose of obtaining information about a person's physical or mental characteristics or aptitude, personality traits, etc. This will include tests that can indicate how a person physiologically handles various nutrients and the like. Some of these tests are located in the grey area between medical and non-medical tests and may be categorised differently depending on the enterprise. This may be tests for tolerance of caffeine, deep sleep, muscle composition, sleep patterns etc. Such tests are often referred to as wellness tests. Furthermore, the expansion will include tests for metabolism and physical properties that may be relevant for body performance, tests related to nutrient absorption (nutrigenetic tests) and tests for taste sensitivity. Tests for mental abilities and personality traits may include tests that examine amusia, crown baldness (hair growth), dandruff, type of earwax, preference for taste, and tests for, e.g., empathy, intelligence, musicality, self-control, etc.

The Ministry also proposes to maintain the current delimitation of the Biotechnology Act's scope, so that genetic testing for identification purposes, e.g., paternity tests and other genealogy tests, still falls outside the scope of the Act. A possible ban on testing children with such tests should be regulated in other legislation.

3.4. Testing outside the health service

The Storting has requested a prohibition against genetic testing of children that will apply outside the health service. In order to ensure sufficient clarity as to how far the prohibition extends, it should be specified what is to be regarded as “outside the health service” in this context. In assessing what is outside the health service, the Norwegian Directorate of Health proposes that the determining condition should be whether health personnel are involved and whether testing takes place within enterprises that are part of / offer health services and are regulated by health legislation. The Ministry agrees with this. However, in the interest of the principle of legality, the delimitation of the prohibition should be further specified.

Therefore, the Ministry proposes that the ban, in principle, be generally applicable, but that exemptions be made for diagnostic testing that has been requisitioned/ordered by a physician / health personnel.

Furthermore, exemptions are made for predictive genetic testing pursuant to Section 5-1, second paragraph, letter b, to the extent that these meet the conditions in the current Section 5-7 (the testing can detect conditions that, through treatment, can prevent or reduce harm to the health of the child) and is carried out by enterprises that are approved pursuant to Section 7-1.

Other genetic testing cannot be carried out on children under 16 years of age, neither in nor outside the health service. This will also include testing to determine sex, cf. Section 5-1, second paragraph, letter c and testing pursuant to the proposed new second paragraph, letter d (testing where the purpose is to gain information about a person's physical or mental characteristics or aptitudes, personality traits, etc.).

3.5. Is there a need to make exemptions from the ban?

The Ministry has assessed whether a comprehensive prohibition should be introduced or whether a safety valve should be included, so that a specific assessment can be made of the best interests of the child.

According to the Ministry's assessment, the prohibition should, in principle, be comprehensive. There do not appear to be considerations that are compelling enough that children should be able to be tested beyond the testing allowed for by the proposed delimitation of the ban. However, the provision in Section 5-7 currently includes a legal authority for the Ministry to make exemptions from the current prohibition against predictive testing of children under 16 years of age in special circumstances. The Ministry proposes to retain this exemption provision in Section 5-7 and proposes that it should also allow the Ministry to make exemptions from the expanded prohibition in exceptional circumstances. The purpose of the legal authority is to ensure an opportunity to safeguard the best interests of the child if this proves necessary. Considering the rapid development in this area, the Ministry believes there is a need for such a safety valve.

3.6. Age limit

The purpose of the prohibition is to postpone genetic testing until the person being tested can personally decide whether or not they want the test and consent to it. In this connection, the Ministry has assessed whether the age limit should be 16 years or 18 years.

In the health service, the age of majority under health legislation is set at 16 years and, pursuant to the Biotechnology Act, the prohibition applies to predictive testing of children under 16 years of age, cf. Section 5-7 of the Biotechnology Act. However, there are some exemptions from the age limit of 16 years for consenting to healthcare. For example, it follows from Section 4-3, first paragraph, letters a and b of the Patient and User Rights Act that the “nature of the measure” may, based on a specific assessment, entail that an 18-year age limit applies. Pursuant to Section 4-5a of the Patient and User Rights Act, patients under 18 years of age cannot consent to cosmetic procedures, injections or treatments without medical or dentistry justification. Parents or others who have parental responsibility for the patient, are also unable to give valid consent to such interventions, injections or treatments. The fact that young people over the age of majority under health legislation have the capacity to consent in most contexts, and that there is no prohibition against predictive genetic testing in the health service after the patient has turned 16 years of age may indicate that the age limit in a prohibition provision against genetic testing of children outside the health service should also be set at 16 years of age.

The Patient and User Rights Act applies in the health service when the person being tested receives health care. The person being tested receives information and follow-up from health personnel, and the genetic information is stored in the health service. Therefore, there are more mechanisms that safeguard the person being tested than with genetic self-tests outside the health service. For testing outside the health service, the conditions are not necessarily suitable for a 16-year age limit as they are with testing in the health service. Therefore, it can be argued that the age limit should be set at 18 years due to the challenges related to guidance and information, the quality of the tests and that it may be difficult for the individual to foresee the consequences of taking such a test.

This applies to the predictive tests, but it may also be difficult to foresee the challenges with other tests that generate genetic information. However, the Ministry is of the opinion that the age limit for the prohibition against genetic testing outside the health service should be set at 16 years of age. As mentioned, this is in line with the general age of majority under health legislation and also the current special regulation of predictive genetic testing of children carried out within the health service. The age limit for cosmetic procedures, injections and treatment without medical or dentistry justification has been set to counteract body-image pressure in relation to young people between 16 to 18 years of age. Experience shows that children and young people are more receptive to body-image pressure than adults and are particularly vulnerable to body-image pressure affecting their self-esteem, self-confidence and mental health. The Ministry does not consider this to be comparable to the prohibition against genetic testing of children outside the health service. The Ministry believes that young people aged 16 are sufficiently mature to foresee the consequences of taking a genetic test outside the health service.

3.7. Penalties

To ensure compliance, it is proposed that the prohibition against genetic testing of children outside the health service be subject to criminal penalties for non-compliance. In the current penal provision in the Biotechnology Act, there are exemptions for private individuals who “seek or use” services that are not permitted under the Act. This exemption should not apply to parents or other private individuals who ensure that genetic tests are carried out contrary to the ban. In order for the prohibition to have sufficient effect and substance, the Ministry believes it is a prerequisite that criminal liability also applies to parents or other private individuals carrying out genetic testing of children outside the health service contrary to Section 5-7 and who contravene the prohibition in Section 5-8, third paragraph. However, private individuals who contravene these provisions should not be punished by imprisonment. In the Ministry's view, fines will be a sufficiently stringent response in such cases.

3.8. Amendments to Section 5-8 on the use of genetic information outside the health and care services

The Ministry proposes that the prohibition in Section 5-8 on the use of genetic information outside the health and care services be expanded to include the use of genetic information derived from testing carried out contrary to the proposed expanded prohibition in Section 5-7. For the sake of the coherence of the legislation, it should not be possible to use information derived from illegal testing. Genetic information derived from predictive testing, cf. Section 5-1, second paragraph, letter b, is already covered by the current prohibition in Section 5-8. The use of information from any predictive testing carried out contrary to Section 5-7 will therefore already be prohibited under the current Section 5-8. The same will apply to any additional predictive information derived from diagnostic testing carried out contrary to an expanded prohibition pursuant to Section 5-7. Any additional predictive information that emerges from a diagnostic test is covered by the prohibition in the current Section 5-8. The Ministry proposes amendments to Section 5-8 so that other genetic information derived from diagnostic testing in violation of Section 5-7 shall also be covered by the prohibition in Section 5-8. Furthermore, the Ministry proposes to amend Section 5-8 so that the prohibition also applies to the use of information obtained when testing children under 16 years of age with the type of tests that the Ministry proposes to include in the definition of genetic testing in Section 5-1, second paragraph, new letter d.

3.9. Amendments to Section 5-2 on the use of genetic testing

Pursuant to Section 5-2 of the Biotechnology Act, genetic testing regulated under the Biotechnology Act may only be carried out for medical purposes if it has a diagnostic or therapeutic objective. Genetic testing under the proposed Section 5-1, new letter d covers testing that has no medical purpose, with diagnostic or therapeutic objective. To avoid a prohibition against the use of such tests for persons over 16 years of age, the Ministry proposes to specify that the provision in Section 5-2 does not apply to genetic tests under the proposed Section 5-1, new letter d.

3.10 Relationship to the Constitution of Norway and other human rights obligations

A prohibition against genetic testing of children outside the health service must be in accordance with human rights in the Constitution of Norway and other human rights obligations. It may be questioned whether a prohibition against genetic testing of children outside the health service is an infringement of the right to respect for private and family life pursuant to Article 102 of the Constitution of Norway, Article 8 of the European Convention on Human Rights (ECHR) and Article 17 of the International Covenant on Civil and Political Rights, in that parents are not permitted to make decisions that they may think are right for their child.

The starting point is that parents make decisions on behalf of their children and compelling reasons are required to limit this right. It is the parents who know their child, the child's preferences and life situation. In other words, the parents are well placed to make choices in the best interests of the child. It is also conceivable that older children themselves want to be tested. On the other hand, children's right to privacy enjoys constitutional protection under Article 104 of the Constitution of Norway and also human rights protection under the Convention on the Rights of the Child and the ECHR, among other things. In the Ministry's assessment, a balancing of interests must be made of the benefits the child may gain from genetic testing being carried out outside the health service, compared to the risk the test poses to the child's privacy. If the benefits do not outweigh the disadvantages, it can be argued that this decision should be postponed until the child can make an informed choice and that the ban safeguards the best interests of the child.

Article 104, second paragraph of the Constitution of Norway states that the best interests of the child shall be a fundamental consideration in all decisions that affect children. Legislative and executive authorities must consider this when decisions are made. Consideration for the best interests of the child can also limit the legislator. Consideration must therefore be given to whether a prohibition against genetic testing of children outside the health service is in the best interests of children, or whether a prohibition would go too far in restricting parents' and children's freedom of choice.

A prohibition against genetic testing of children outside the health service means that children are not given the opportunity to be tested if they do not have an offer from the health service, including where the parents, other advisors and perhaps also the child themselves believe that the testing will be in the best interests of the child. The parents will then be dependent on appealing against the lack of offers in the public sector or availing themselves of any private offers.

However, the proposed prohibition only applies to genetic testing of children outside the health service. If a predictive genetic test can detect conditions that, through treatment, can prevent or reduce harm to the health of the child, the test can be carried out in the health service in accordance with Section 5-7 of the Biotechnology Act. A prohibition against genetic testing of children outside the health service will thereby not make it impossible for children with a need for genetic testing to undergo the test. However, the prohibition will ensure that children are only tested in the health service. Thereby, it is ensured that children are not tested against their will by parents, that the test has a medical purpose and that the

child and family receive adequate guidance from health personnel in connection with testing and results. In other words, the starting point for the prohibition is that any benefit from testing outside the health service is so limited or uncertain that it generally will not outweigh the potential disadvantages testing might have for children.

It also follows from Article 104, third paragraph of the Constitution of Norway that children have the right to protection of their personal integrity. This, and considerations for children's privacy, are considerations that must be emphasised in an assessment of what is in the best interests of the child. It is clear that genetic testing of children without the child having had the opportunity for co-determination or contrary to the child's expressed will is a serious infringement of the personal integrity of the child. Genetic information may reveal information about identity and kinship and can predict the risk of diseases. Furthermore, such data can provide information related to the child's biological relatives, and the child will thereby receive genetic information that is of significance to more people than themselves. This may be information that is burdensome for a child to receive. Considerations for the child's personal integrity and privacy indicate that the child should have a right to an open future. In order to safeguard a desire not to know about any disease or disease risk, such tests should, in the Ministry's assessment, be postponed until the child is sufficiently mature to decide whether they want this information.

Another consideration is that if information goes astray, e.g., if data are shared with third parties or others without the child's or family's knowledge, the harm cannot be rectified. Many of the companies that offer genetic self-tests are based in the United States. Several companies share user data with third parties. The agreements that the consumer enters into with the companies are often highly complex and it is often difficult for the consumer to understand the content and scope of the agreement. This makes it more difficult to form an overview of the use of the information and an overview of the rules for managing the information. Therefore, such self-tests challenge privacy to a great extent, and it can be argued that children, in particular, require additional protection of their personal integrity and privacy. Therefore, the Ministry believes that it is in the best interests of children to introduce a prohibition against genetic tests outside the health service, and that the prohibition is in accordance with Norway's human rights obligations.

3.11 Relationship with EEA legislation

A prohibition against testing of children outside the health service would limit the possibility of selling testing services and testing equipment to consumers in Norway.

In principle, the EEA Agreement prohibits restrictions on what is known as free movement of goods and services across national borders. A national prohibition against testing of children outside the health service and the sale of genetic tests to children will affect testing services and test equipment that consumers can purchase regardless of whether the provider is established in Norway, the EEA or in third countries. The consequences of the bans will be the same for foreign as for Norwegian providers. Although the bans do not discriminate against domestic and foreign providers of products or services, they will limit access to the Norwegian market and thereby constitute a restriction on trade in the EEA.

National measures that constitute restrictions on the free movement of goods or services may be maintained if they pursue a purpose or consideration that can be invoked in accordance with the EEA Agreement or case law of the EFTA Court, and if the measure is deemed suitable and necessary to achieve the purpose.

The Ministry assumes that the prohibition against testing of children outside the health service and the prohibition against selling certain genetic tests to children will amount to restrictions on the free movement of both goods and services. The topics of assessment as to whether the bans are legitimate are nevertheless approximately the same, and the Ministry therefore makes a single, joint assessment, below. The Ministry first considers whether a prohibition against testing children under 16 years of age outside the health service and a prohibition against selling genetic tests to children are to be regarded as safeguarding a public interest.

The purpose of introducing the bans is to safeguard children's integrity and privacy. Safeguarding children's integrity and privacy is not one of the statutory exemptions in Article 13 for goods and Article 33 for services in EEA Agreement. In accordance with case law from the EFTA Court, states may, however, in specific situations also invoke other considerations than those determined by law.

The protection of personal data is safeguarded by the EU's General Data Protection Regulation (GDPR). Paragraph 10 of the GDPR preamble states: *"(...) This Regulation also provides a margin of manoeuvre for Member States to specify its rules, including for the processing of special categories of personal data ('sensitive data'). To that extent, this Regulation does not exclude Member State law that sets out the circumstances for specific processing situations, including determining more precisely the conditions under which the processing of personal data is lawful."*

The GDPR provides a national margin of manoeuvre, and this right expressly follows from Article 9, subsection 4 of the GDPR:

Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.

Any limitations that are adopted nationally to safeguard considerations that fall under this provision of the Regulation must be regarded as fulfilling the condition that they must safeguard a "lawful" consideration.

Children are also given special protection in the Convention on the Rights of the Child, and children and persons who do not have capacity to consent are granted special protection in the Convention on Human Rights and Biomedicine and the Additional Protocol concerning Genetic Testing for Health Purposes.

Case law from the EFTA Court shows that fundamental human rights principles can also be regarded as legitimate public interests that can justify limitations on the free movement of goods and services. Therefore, the Ministry is of the view that it can be argued that

considerations for the integrity of children, including that the decision to carry out genetic testing should be postponed until the child can personally make the decision, is a legitimate public interest. Both the GDPR and the In Vitro Diagnostic Regulation (IVDR) recognise that genetic data is in a unique position. In addition to pursuing overriding reasons in the public interest, the measure must be proportionate. This means that the measure must be suitable and necessary to achieve the purpose.

The Ministry first considers whether the prohibition against testing children outside the health service and selling genetic tests to children is suitable to safeguard the purpose of children's integrity and privacy. This is an assessment of whether the objective can be achieved with the measure. The purpose of a prohibition is to safeguard children's integrity and privacy with regard to the generation and processing of genetic information outside the health service. The prohibition does not apply to all testing, but to testing of children outside the health service.

A prohibition will entail that Norwegian enterprises cannot offer such services or tests in Norway and will also affect the possibility of marketing from abroad aimed at Norway. Among other things, the prohibition targets carrying out tests of children in Norway and will therefore also affect the use of the tests in Norway. Therefore, the Ministry assumes that the prohibition is suitable for safeguarding children's integrity and privacy with regard to the generation and processing of genetic information outside the health service.

When assessing whether the measure is necessary, an important element is whether the purpose can be achieved by less intrusive means. A less intrusive measure than a prohibition is to ensure information to the population regarding the product. However, genetic tests are complicated in terms of the quality of the test and the results of the test, what information is generated about the person being tested and how the information is processed. Furthermore, in the case of genetic self-testing, the consumer will initially have access to the test results online, and genetic counselling is usually not included when purchasing a genetic self-test. Some companies offer 30–45 minutes of genetic counselling as a service that can be purchased separately. The genetic self-tests are different, and it is difficult for the health authorities to provide sufficient general information and guidance about the tests. Furthermore, it can be difficult to disseminate sufficient information for the entire population. Therefore, the Ministry is of the view that information to consumers regarding genetic testing, including genetic self-tests, is not sufficient to safeguard children's integrity and privacy.

In drafting the proposed ban, it has been emphasised that the prohibition should not have a wider reach than is necessary to achieve the purpose of safeguarding children's integrity and privacy. Scope is therefore provided for genetic diagnostic testing that is requisitioned/ordered by health personnel/physician. Predictive genetic testing may also be carried out if an approved enterprise considers that the test is necessary because it “can detect conditions that, through treatment, can prevent or reduce harm to the health of the child”.

Thus, the prohibition will not affect situations where the health service considers that the test has a medical benefit. The most important distinction between genetic tests performed in the health service and genetic self-tests to test for disease, disease risk or other medical factors, is that private individuals order the self-test directly from a company, without there being a requirement for medical assessment of need or potential benefit, in advance. Companies do not have to adhere to the priorities and the same requirements for medical benefit as the health service and can thereby also offer tests related to health that are of less clinical value. Furthermore, the age limit is set at 16 years. It has also been proposed that the Ministry shall have legal authority to make exemptions from the prohibition in special circumstances.

On this basis, the Ministry is of the view that the purpose of safeguarding the integrity and privacy of children cannot be achieved by less intrusive means, and that the proposed bans thereby represent a lawful limitation in accordance with the rules of EEA legislation on the free movement of goods and services. The prohibition will be a technical rule according to the definition in Section 3 of the EEA Consultation Act. The proposal shall therefore be reported to the EFTA Surveillance Authority (ESA), cf. Section 4 of the Act.