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# An Overview of the Recent Case Law of the Constitutional Court of the Republic of Latvia

**Abstract.** The article highlights recent trends in the case law of the Latvian Constitutional Court with regard to the response to COVID-19, empowerment of marginalised groups, and protection of democracy. These developments emphasise the Court's role in upholding the rule of law, promoting equality, and safeguarding democracy in Latvia. During the pandemic, its rulings shaped the legal framework for managing the crisis while balancing public health against individuals' rights. Analysis shows that the decisions on emergency measures, restrictions to fundamental rights, and executive powers ensured government actions' legality and proportionality, with the Court demonstrating commitment to empowering marginalised groups through case law addressing gender equality, LGBTQ+ rights, minority rights, and disability-related rights. The paper shows how, by providing legal protection and promoting inclusivity, the Court advanced the rights of marginalised communities while, additionally, protecting democracy remained a paramount concern for the institution, whereby it safeguarded the Latvian constitutional order, separation of powers, independence of the judiciary, and the rule of law. The discussion illustrates how vigilant scrutiny of legislation and government actions can preserve democratic values, uphold the integrity of institutions, and ensure accountability.

**Keywords:** COVID-19 pandemic, empowerment of marginalised groups in society, protection of democracy, constitutional court, case law

## Introduction

Since the beginning of 2020, the Constitutional Court of the Republic of Latvia (hereinafter 'the Court') has delivered rulings in more than 80 cases which concerned a broad variety of issues, including protection of personal data, the use of the official (Latvian) language in education, the SARS-CoV-2 pandemic, the safety of and access to the Latvian natural-gas pipeline network, and LGBTQ+ rights if we confine ourselves to naming only a few. This paper offers an overview of selected rulings of the Court by categorizing them into three groups which reflect the recent trends in the case law of the Court: the COVID-19 pandemic, empowerment of marginalised groups in society, and protection of democracy.

# Cases related to the SARS-CoV-2 pandemic

In March 2020, the World Health Organization announced that the global COVID-19 outbreak caused by a coronavirus had reached the level of a pandemic.[*1] Shortly after that, the Latvian government (through the Cabinet of Ministers) issued an order declaring a state of emergency for approximately a month.[*2] It was later prolonged for a few months and issued again two times over the course of the next two years. This allowed room for swift epidemiological safety measures and related human rights restrictions most of which were established by the government. Several of these measures were contested before the Court resulting in over 100 complaints. Most of the said complaints were related to the obligation to wear medical face masks; limitations on assembly, association, and religious activity, limitations of business hours and commercial activity in shopping centres; the 'downtime allowance' paid by the state to workers; and vaccination. However, only some of these complaints fell within the jurisdiction of the Court or were substantiated enough for a case to be initiated before the Court.

## Restrictions on gambling businesses (Case 2020-26-0106)

The first SARS-CoV-2-pandemic-related judgement of the Court concerned temporary prohibition of in-person gambling as well as interactive gambling during the state of emergency.[*3] The case was initiated on the basis of constitutional complaints submitted by five companies who organize gambling; they claimed that such prohibition, amongst other, violates their right to property as enshrined in Article 105 of the Latvian Constitution (the Satversme)[*4]. The Court reiterated that the right to operate a particular type of business under a licence (namely, organising in-person and/or interactive gambling in this case) indeed falls within the scope of Article 105 of the Constitution and, hence, that the applicant's right to property had indeed been restricted. The restriction had been imposed in order to ensure protection of other people's rights regarding public-health concerns and of public welfare.

The Court concluded that the restriction to in-person gambling was both appropriate and necessary as it contributed to limiting the spread of the virus in a timely fashion, since the principal mode of transmission of the virus was through respiratory droplets that are expelled when a person speaks, coughs, or sneezes. Namely, physical contact and meetings had to be limited. However, the restrictions on interactive gambling did not help to limit the spread of COVID-19. Even though they could have contributed to protecting the financial situation of individuals during the pandemic, the Court noted that even during the emergency situation, the legislator must not adopt provisions that are unreasonably broad and also restrict the rights of those individuals to whom the legitimate aim of the regulation does not at all apply. Namely, when adopting a provision aimed at protecting individuals with gambling problems and their families, the legislator had no reason for simultaneously restricting all other people's right to choose where to invest their funds and thereby interfere with how they wished to spend their free time. It was furthermore established that, what could be regarded as alternatives to the means of achieving the legitimate aims are specific restrictions on the course of interactive gambling, for example, limiting the time and money spent on the gambling websites. Thus, the Court found that the restrictions imposed on interactive gambling were not necessary in the context of proportionality test and therefore did not comply with the Constitution.

In this case, the Court elaborated on how proportionality should be applied together with the precautionary principle which grants the legislator a wider margin of appreciation. Namely, if the resort to the precautionary principle as such is reasonably justified, whenever there is a qualified and serious risk to health and welfare whenever there is a qualified and serious risk to health and welfare, the State does not have to wait until the risk becomes reality. However, the restrictions adopted by the legislator, on the basis of such precaution, still have to be in line with the Constitution. Furthermore, it was established that that in

1 'WHO Director-General's Opening Remarks at the Media Briefing on COVID-19 – 16 March 2020' <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---16-march-2020> accessed 10 June 2023.

2 Cabinet Order 103, of 12 March 2020: 'Regarding Declaration of the Emergency Situation' [2020](51A) Latvijas Vēstnesis.

3 This was the judgement of 11 December 2020 by the Constitutional Court of the Republic of Latvia in Case 2020-26-0106, 'On Compliance of Section 9 of the Law "On Measures for the Prevention and Suppression of Threat to the State and Its Consequences Due to the Spread of COVID-19" with Article 105 of the Constitution of the Republic of Latvia and Article 49 of the Treaty on the Functioning of the European Union' [2020](242) Latvijas Vēstnesis.

4 Available in English at <https://likumi.lv/ta/en/en/id/57980> accessed on 10 June 2023.

cases wherein the legislator is faced with great uncertainty and believes that the achievement of particular aims requires quick solutions, there is no necessity for the legislature to conduct lengthy, in-depth research into the threat of the respective damage or hold detailed debate on the prevention of the damage as these would significantly delay the adoption and effectiveness of the decision. The Court expressed ideas along similar lines in other cases related to the SARS-CoV-2 pandemic.

## Testing for the virus prior to entry to Latvia (Case 2021-10-03)

The case was initiated on the basis of an application submitted by a citizen of Latvia who had been residing in Germany for several years. The applicant had made a habit of travelling to Latvia, had planned to do so in 2021 by passenger air transport in the second half of January or in February; however, the Latvian government had set forth several restrictions on travelling, including the requirement for a negative COVID-19 test result before boarding a passenger air transport that is flying to Latvia. The applicant held that said requirement imposed a disproportional restriction on her as a citizen's right to freely return to Latvia as enshrined in Article 98 of the Constitution.

The Court found that the right of Latvia's citizens to freely return to Latvia was absolute and could not be restricted. However, it was noted that there are various ways in which a citizen of Latvia could return to Latvia, for example, by crossing the land border or entering through a port, airport, railway station, or otherwise. Thus, the Court concluded that a person's right to return to Latvia should be differentiated from a person's wish and possibility to use a particular type of transportation for this purpose.

The Court found that entering the territory of Latvia was not restricted, for example, for the citizens of Latvia who entered Latvia by vehicle that was not providing commercial transportation services and who had tested positive for SARS-CoV-2. Additionally, it was noted that the contested norm could indeed have caused certain inconvenience for the person because it impeded traveling in the manner she desired. However, this could not be regarded as an insurmountable obstacle as Latvia had not prohibited its citizens from traveling and had not closed its borders. Hence, the Court concluded that the applicant's right of freely returning to Latvia had not been restricted, and the proceedings were terminated accordingly.[*5]

## Restrictions on operations at shopping centres (Case 2021-24-03)

The case concerned an epidemiological safety provision set forth by the Cabinet of Ministers that stipulated that operation of shops in the shopping centres, the total area dedicated to trade of which exceeded 7000 square meters, was prohibited, except for certain categories of shops. It was initiated on the basis of applications submitted by companies running shops on the premises of these shopping centres that have the possibility to ensure entrance to these shops from the outside, as well as the owners of shopping centres who lease their premises to traders and service providers. The applicants argued the contested regulation creates inequality and is incompatible with the right to property as it provided that only a selection of shops could operate in large shopping centres.

The Court held that the rights of shop owners had been restricted but the said restriction was imposed in order to curb the spread of the virus behind COVID-19 by limiting the gathering and mobility of people in large shopping centres and consequently decreasing the load on public transportation. Thus, the regulation pursued the legitimate aim of protection of other persons' right to health. Additionally, uncontrolled spread of SARS-CoV-2 could have caused an overload for the health sector, thus jeopardising the continuity of accessibility of health care and medical services. Hence, protection of public welfare was also acknowledged as a legitimate aim of the restriction. Furthermore, the Court concluded that the restrictions did contribute to achieving these aims. Nevertheless, the Court found that other measures existed that would restrict the shop owners' fundamental rights to a lesser extent and would ensure the fulfillment of the legitimate aims in the same quality. Namely, there were no significant differences between a shop located in a large shopping centre that had been zoned off from the common use premises and to which an entrance from the outside had been ensured, and a shop set up outside a shopping centre's premises. Thus, regulation permitting such shops in large shopping centres to continue operating would allow to achieve the authorities' legitimate aims in the same quality.

[5] Per the decision of 18 February 2022 by the Constitutional Court of the Republic of Latvia in Case 2021-10-03, on the compliance of para $35^3$ of Cabinet of Ministers Regulation 360, of 9 June 2020, 'Epidemiological Safety Measures To Contain the Spread of COVID-19 Infection', with the second sentence of Article 98 of the Constitution of the Republic of Latvia. See 22 February 2022's *Latvijas Vēstnesis* (37).

Therefore, the Court concluded that the contested regulation, insofar as it applied to shop owners, violated their right to property and was incompatible with Article 105 of the Constitution. To this extent, the contested regulation was also deemed incompatible with the principle of equality as enshrined in the Constitution's Article 91, because it prohibited the operation of those shops in large shopping centres irrespectively of whether separate entrance from outside could be ensured for the particular shop. Meanwhile, stand-alone shops set up in other trading venues could continue their operations.

Regarding the owners of shopping centres, the Court recognised that the possibility for them to benefit from leasing their premises was closely connected to the tenants' rights to use these premises for trading. Thus, the contested regulation substantially stripped the owners from exercising their right to lease their premises out and profit from their property respectively. Nevertheless, the entire society benefited from the contested regulation as it protected both people themselves from falling ill and the health care system from becoming overloaded. In view of the spread of the virus and the threats it posed for the health system, the legitimate interests of some commercial companies could not be placed above the interests of the entire society. Thus, the Court recognised that the contested regulation, insofar as it applied to owners of large shopping centres, complied with the right to property as enshrined in Article 105 of the Constitution. However, the Court deemed it incompatible with the principle of equality as enshrined in Article 91 of the Constitution. The contested regulation allowed trading within the premises of a large shop. On the other hand, with certain exceptions, trade was not allowed in large shopping centres during the whole time the contested regulation was in force. Hence, the contested regulation foresaw differential treatment of these groups. The Court did not identify objective arguments allowing to conclude that the differential treatment of owners of large shopping centres and owners of large shops had a legitimate aim.[*6]

### Conclusions from the COVID-19-related cases

The Court has also adjudicated a case concerning regulation stipulating that school students shall receive all their primary and general secondary education remotely, due to spread of SARS-CoV-2. The remote learning regulation was deemed to comply with the school student's right to education as enshrined in Article 112 of the Constitution. Furthermore, there are two cases that are still pending before the court. One is related to prohibition to import mink in Latvia during the pandemic, but the other is related to the obligation for members of Parliament to be vaccinated against the coronavirus before being permitted to carry on fulfilling their duties.

An overarching view that the Court has taken in the COVID-19 pandemic related cases is that the proportionality principle should be applied together with the precautionary principle which grants the legislator a wider margin of appreciation. Namely, if the resort to the precautionary principle as such is reasonably justified, whenever there is a qualified and serious risk to health and welfare, the State does not have to wait until this risk becomes reality. However, the restrictions adopted by the legislator, on the basis of such precaution, still have to be in line with the Constitution. Furthermore, it has been established that that in cases when the legislator is faced with great uncertainty and believes that the achievement of particular aims requires quick solutions, there is no necessity for the legislator to conduct lengthy, in-depth research about the threat of the respective damage or hold detailed debate on the prevention of the damage as these would significantly delay the adoption and effectiveness of the decision. These ideas might be followed by the Court in other COVID-19 pandemic related cases.

## Cases related to empowerment of society's marginalised groups

Another reoccurring theme in the recent case law of the Court has been the empowerment of marginalized groups of society. These cases showcase the need to protect vulnerable minorities from the uncontrolled and more often than not biased rule of the majority.

6 See the judgement of 10 March 2022 by the Constitutional Court of the Republic of Latvia in Case 2021-24-03, 'On Compliance of Paragraph 2418 of the Cabinet of Ministers Regulation No 360 of 9 June 2020 "Epidemiological Safety Measures for the Containment of the Spread of Covid-19 Infection" (in the Wording That Was in Force from 7 April 2021 until 19 May 2021) with the First Sentence of Article 91, [and] the First and the Third Sentence of Article 105 of the Constitution of the Republic of Latvia' [2022](51) Latvijas Vēstnesis.

## Poverty and guaranteed minimum income (Case 2019-24-03)

In summer 2020, the Court passed judgement in a case which concerned the guaranteed minimum income (GMI) level set forth by the government (Cabinet of Ministers).[*7] This indicator was supposed to represent the amount of money a person needs to cover their basic needs. According to Latvian law, it is used to determine the amount of GMI benefit – a material support in monetary terms provided to eligible persons in need for covering their everyday expenses. At the time of adjudication of the case, the contested provision stated that the amount of GMI level for a person shall be 64 euros per month.

The case was initiated on the basis of the Ombudsman's application. The Ombudsman held that this GMI index was incompatible with the core principle of a welfare state and with the principle of the rule of law because it does not assure needy persons of a life compatible with human dignity and does not honour the obligation to ensure that people have an opportunity to exercise their social rights at least to a minimal extent in accordance with the guarantees of Article 109 of the Constitution.

The Court reiterated that the legislator is obliged to create a social-security system that is aimed at the protection of human dignity as the overarching value of a democratic state governed by the rule of law. For everyone to be able to lead a life compatible with human dignity, the minimal social assistance should be such that anybody could provide food, clothes, housing and medical assistance for themselves – everything that is needed to guarantee elementary survival to any person, as well as to ensure to any person the possibility to exercise their right to primary education. Moreover, social assistance should guarantee to a person the possibilities to participate in social, political, and cultural life, thus, ensuring this person the status of a full-fledged member of society.

The Court found that the legislator had introduced measures to create a system of social security, thus ensuring to persons the possibility to exercise their right to social security. One of the elements in the system of social security is social assistance, the purpose of which is to provide assistance to needy persons and which comprises the GMI level, set in the contested norm, and the benefit linked to it. However, the GMI level itself was set by the Cabinet of Ministers, not Parliament, even though it was a parliamentary duty to decide on this essential issue. Furthermore, the Court established that the GMI level of 64 euros was based on a mere agreement between the institutions involved in the payout of the GMI benefit, namely, the Cabinet of Ministers and local governments. There was no method behind it that would ensure that the GMI level actually contributes to ensuring the basic needs of the GMI benefit recipient.

Other measures of the social security system available to needy persons in addition to the benefit for ensuring GMI level were also examined by the Court. It recognised that, within the framework of the social-security system, various measures of social assistance were available to a needy person. However, the state social benefits could not be assessed as benefits to be used to satisfy a person's basic needs since they have other objectives. Moreover, they were granted to persons belonging to certain groups of inhabitants in concrete situations. Thus, the Court found that the GMI level set in the contested norm, in interconnection with other measures of the social-security system, did not ensure that every needy person could lead a life that would be compatible with human dignity. Hence, the contested norm was found incompatible with Article 1 and Article 109 of the Constitution.

## Reintegration of ex-convicts into society (Case 2020-36-01)

The Court has adjudicated several cases which were related to permanent bans imposed on ex-convicts even after their criminal record had been cleared. These bans mostly manifest as restrictions on formal recognition of their family ties as well as access to certain jobs.

In March 2021, the Court delivered a judgement in a case concerning a norm which prohibits a person convicted of a violent criminal offence from being employed in contact with children for life.[*8] This case was initiated on the basis of an application submitted by the Supreme Court. It stated that the employer, on the basis of the contested norm, terminated the employment relationship with an employee who worked as a building supervisor and had been convicted of malicious hooliganism.

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7 The judgement of 25 June 2020 by the Constitutional Court of the Republic of Latvia in Case 2019-24-03, 'On Compliance of Para 2 of the Cabinet Regulation of 18 December 2012 No 913 "Regulation on the Guaranteed Minimum Income Level" with Article 1 and Article 109 of the Constitution of the Republic of Latvia' [2020](121) Latvijas Vēstnesis.

8 Case 2020-36-01, with the judgement titled 'On Compliance of Para 1 of Section 72(5) of [the] Law on the Protection of the Children's Rights with the First Sentence of Article 91 and the First Sentence of Article 106 of the Constitution of the Republic of Latvia' [2021](62) Latvijas Vēstnesis.

Firstly, the Court held that all forms of violence against children must be prevented in the first place by proactive and preventive measures. The contested provision also provided for such measures. It minimised the likelihood of direct and continuous or regular contact with children by a person whose past behaviour has been directed at endangering another person by using or threatening violence. Furthermore, the Court reiterated that in cases where a decision is adopted by weighing various interests involved, including the interests of the child, the best interests of the child have the highest priority. But this does not mean that other interests should not be taken into account. In this case, the best balance must be found between all the interests involved. The right to choose employment is also an important fundamental right, as work is an indispensable source of human dignity and affirmation in a democratic society.

Secondly, the Court emphasised that the legislator is entitled to establish such a prohibition (whereby a convicted person may not be employed in contact with children) only if said person objectively poses a greater risk of danger to a child than someone who has not been convicted of a crime. The mere fact that a person has been convicted of a violent crime is not always sufficient to establish that they pose risk to children in the longterm. The prohibition of a restriction on a fundamental right should not be based on general presumptions, but should, as far as possible, promote the achievement of individual justice. The Court held that the right of a person convicted of a violent criminal offence to be employed in contact with children may be assessed individually by the head of the institution, the employer or the event organiser, if necessary in consultation with the State Inspectorate for Protection of Children's Rights. The State Inspectorate for the Protection of Children's Rights could also be given such additional competence, and such an assessment could also be made by a court of general jurisdiction. Consequently, the legitimate aim of the restriction of fundamental rights could be achieved in the same quality by means which were less restrictive of the rights of persons and which, moreover, did not require a disproportionate contribution from the state and society. Thus, the restriction of fundamental rights contained in the contested provision was not proportionate and the contested provision did not comply with Article 106 of the Constitution.

## LGBTQ+ rights (Case 2019-33-01)

The case concerned a legal norm that did not envisage the right to a leave in connection with the birth of a child to the female partner of the child's mother.[*9]

The case was initiated on the basis of a constitutional complaint. It was noted therein that the applicant was in a stable same-sex relationship with her partner. After they began cohabiting, two children were born to the applicant's partner, and the applicant and her partner had jointly planned their birth. Both children lived in a common household with the applicant and her partner. Immediately after the birth of the youngest child, the applicant had wanted to take the leave of 10 calendar days to be together with the new-born child in the first moments of his life and to provide support to her partner. However, the contested legal provision envisages the right to this leave only to the father of the child but does not envisage this right to the female partner of the child's mother, who in fact should be considered as being one of the new-born child's parents. Thus, the legislator had not fulfilled its duty to ensure protection and support to a family with same-sex partners.

Firstly, the Court noted that the state's obligation to protect marriage as a union between a man and woman is set forth in the first sentence of Article 110 of the Constitution. At the same time, this norm establishes an obligation on the state's part to protect and support the family, parents, and children too. The Court underscored that this obligation did not apply only and solely to a family established through marriage. Thus, the first sentence of Article 110 of the Constitution defines a positive obligation of the state to protect and support all families, also, *inter alia*, *de facto* families established through cohabitation. The Court also noted that Article 110 of the Constitution did not specify the concept of family and did not advance gender as a criterion for determining the persons who should be recognised as being a family. In this regard, it recognised that society consisted not only of such persons who, as to their nature, formed close personal and family ties with the representatives of a different sex, but also of persons who, as to their nature, formed such relationships with the representatives of their own sex.

[9] The Constitutional Court ruled on this on its judgement of 12 November 2020 in Case 2019-33-01, 'On Compliance of Section 155(1) of the Labour Law with the First Sentence of Article 110 of the Constitution of the Republic of Latvia' [2020] (222) Latvijas Vēstnesis.

Secondly, the Court recalled that human dignity was the constitutional value of the State of Latvia. The view that the dignity of one human being could be of a lesser value than the dignity of another human being is incompatible with the principle of human dignity. The principle of human dignity does not allow the state to derogate from ensuring fundamental rights to a certain person or a group of persons. The stereotypes prevailing in the society may not serve as constitutionally justifiable grounds for denying or restricting the fundamental rights of a certain person or groups of persons in a democratic state governed by the rule of law.

Lastly, the Court concluded that, in a family of same-sex partners, legal protection and the measures of social and economic protection were accessible only to the mother and her child. Thus, substantially, the protection and support accessible to the family of same-sex partners did not differ from the protection and support that is accessible to the family consisting only of a mother and her child. Thus, the existing legal regulation of family relationships did not ensure protection and support to same-sex partners and to the children born into their families as a united family. The legislator had not established legal regulation of family relationships of same-sex partners, and had not envisaged for families of same-sex partners measures of social and economic protection and support in relation to the birth of a child. Thus, the legislator had not fulfilled its positive obligation deriving from Article 110 of the Constitution to ensure legal, social and economic protection also to families of same-sex partners. Consequently, the Court recognized the contested norm as being incompatible with Article 110 of the Constitution.

### Concluding remarks on case law related to empowerment of marginalised groups

The case law related to empowerment of marginalised groups in society reveals human dignity as an overarching value and fundamental right used to determine the constitutional framework within which these cases should be adjudicated. It remains important to this day, as many of the groups mentioned here are still sometimes seen as inherently inferior and less valuable to society.

## Cases related to protection of democracy

Another topical issue highlighted in the recent case law of the Court is protection of democracy. The Court has adjudicated cases related to voting rights of prisoners, financing of political parties, as well as militant democracy measures set forth in the Criminal Law.

### Voting rights of persons serving a custodial sentence (Case 2021-43-01)

In November 2022, the Court passed a judgement in a case concerning a norm in Latvian law according to which persons who are serving a sentence in places of deprivation of liberty have no right to elect the council of a local government.[*10] The case was initiated on the basis of an application of an individual who was serving a custodial sentence and as such was subjected to the contested norm. This individual claimed that the prohibition established by the contested provision restricts the right of a person to participate in the election of local government by voting as set forth in the first sentence of Article 101 of the Constitution.

The Court recognized that the contested norm unjustly and automatically restricted the fundamental right to elect local government for a group of individuals based solely on the fact that they were serving a custodial sentence in a place of detention. The norm in question, however, failed to take into account whether there was a logical and sufficient connection between the restriction of the right to vote and the specific criminal offense committed by the individual, as well as their unique circumstances. As such, individuals serving a custodial sentence in a place of detention should not be exposed to greater restrictions than what is necessary due to the nature of their offence and the type of punishment imposed on them.

[10] The judgement of 3 November 2022 by the Constitutional Court of the Republic of Latvia in Case 2021-43-01, 'On Compliance of Section 6(2) of the Law on the Election of Local Government Councils with the First Sentence of Para 2 of Article 101 of the Constitution of the Republic of Latvia' [2022](216) Latvijas Vēstnesis.

The Court also emphasized that the restriction of suffrage for individuals serving a sentence at a place of deprivation does not effectively encourage civic engagement or successful reintegration into society upon release. A general restriction on suffrage is also at odds with the goal of criminal punishment, which is to rehabilitate and reintegrate the individual into society. Furthermore, the Court observed that any limitations on the right to vote must be evaluated in relation to the democratic progress of the state. Specifically, it is crucial to regularly reassess the necessity of such limitations, taking into account the level of democratic maturity of the society and the state at the given time.

As a result, the Court found the contested provision to be incompatible with right of a person to participate in the election of local government by voting as set forth in Article 101 of the Constitution.

## Democracy capable of protecting itself (Case 2021-34-01)

In May 2022, the Court terminated proceedings in a case concerning a criminal-law provision which criminalized a public call to eliminate national independence of the Republic of Latvia.[*11] The case was initiated on the basis of a constitutional complaint of an individual who had published an appeal on a Web site calling for collecting signatures for the Republic of Latvia to join the United States of America. By a judgement of a court of general jurisdiction, the applicant was found guilty of the criminal offence provided for in the contested norm. The applicant considered that this norm infringed his right to freedom of expression as enshrined in Article 100 of the Constitution.

The Court interpreted the contested norm and concluded that this norm provided for criminal liability only for such a public call to eliminate the national independence of the Republic of Latvia, which poses a real threat to the interests of the state and society and incites to such an action that would actually enable the aim of the call to be achieved. Furthermore, the Court emphasised that the contested norm in the state's criminal law served to protect the state and its democracy. This norm contributed to the implementation of the principle of democracy capable of protecting itself. It was also recognized that the objective purpose of the contested norm of the Criminal Law was to target persons who made such public calls for the elimination of national independence which exceed the limits of freedom of expression and pose a real threat to the national independence and democratic state system of the Republic of Latvia.

The Court recognized that its interpretation of the contested norm of the criminal law ensured protection of the fundamental rights of a person enshrined in Article 100 of the Constitution. In such a way, by interpreting and applying the contested norm in accordance with the Constitution ruled out any grounds for doubting its constitutionality along the way. Thus, the Court recognized the applicant's assumption that the conflict of legal norms with legal norms of higher legal force was caused by the contested norm of the criminal law as unfounded. Whereas assessing the actual circumstances of the criminal case and the qualification of the offence committed by the person did not lie within the competence of the Court, the proceedings connected with the contested criminal-law norm's compliance with Article 100 of the Constitution were terminated.

## Concluding remarks on cases related to protection of democracy

The case law related to protection of democracy suggests that the understanding of democracy, rule of law and human rights might still not be sufficient within the society of Latvia and the Parliament, too.

In order to change that, the Court has taken part in several projects to maintain a dialogue with both the society and other state institutions. These include drawing and writing competitions for school students, annual meetings with representatives of state institutions as well as active engagement with the media.

[11] The Constitutional Court of the Republic of Latvia made this ruling in its 27 May 2022 decision on Case 2021-34-01, on the compliance of Section 82(1) of the Criminal Law in the wording that was in force from 1 April 2013 until 10 May 2016 with the first sentence of Article 100 of the Constitution of the Republic of Latvia and on the compliance of the transitional provision of the law of 21 April 2016, 'Amendments to the Criminal Law', with Article 1 and the second sentence of Article 92 of the Constitution of the Republic of Latvia', per *Latvijas Vēstnesis* 103, of 30 May 2022.

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# The Public Interest Requirement in the Secondary Use of Health Data in Scientific Research:

## The Examples of Estonia and Finland

**Abstract.** The General Data Protection Regulation (GDPR) foresees a flexible data processing regime for conducting scientific research with health data. This regime also enables extensive limitations on data subjects' rights to privacy and self-determination. Concern has been expressed that the notion of 'scientific research' may encompass conducting also profit-oriented commercial research that might not justify such limitations to data subjects' rights. Some authors have suggested a restriction on benefiting from the flexible scientific research regime: public interest should be set as a prerequisite for any scientific research employing health data without the data subject's consent. While the GDPR does not explicitly require that scientific research be in the public interest, it allows Member States to choose their policies. In light of this, the article examines the examples of Estonia and Finland to analyse whether national law should require the processing of health data in scientific research in the absence of the data subject's consent to be in the public interest. The article demonstrates on the basis of the two countries' examples that it is possible to set a public interest standard without explicitly requiring the existence of a public interest via national legislation. Considering the future, the article also shows that, under the proposed European Health Data Space regulation, Member States may retain the public interest standard through the ethics-review requirement in their national law.

**Keywords:** health data, scientific research, secondary use, public interest, GDPR, European Health Data Space

## 1. Introduction

There is ongoing discussion about what constitutes 'scientific research' in the meaning of the General Data Protection Regulation[*1] (GDPR), Article 9 (2)(j).[*2] The question is crucial because the associated scientific

1 Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L119/1 (GDPR).

2 Rossana Ducato, 'Data Protection, Scientific Research, and the Role of Information' (2020) 37 Computer Law & Security Review 105412, 2–4. – DOI: https://doi.org/10.1016/j.clsr.2020.105412; Heidi Beate Bentzen, 'In the Name of Scientific Advancement: How To Assess What Constitutes "Scientific Research" in the GDPR To Protect Data Subjects and Democracy'

research regime enables extensive limitations to data subjects' rights to privacy and self-determination. If the activity falls within the scope of scientific research in the meaning applied by the GDPR, the researcher may escape from the need to obtain data subjects' consent and also be exempted from following some basic principles set forth in the GDPR – e.g., those for storage limitations and transparency.[*3] In addition, the European Union (EU) or national law may allow derogations from data subjects' rights, among them the data subject's right to access one's data.[*4] This makes the scientific research regime attractive not only to academic researchers but also to commercial entities conducting profit-oriented research. Concern has been expressed that commercial research might not contribute to the common good to an extent sufficient for justifying such a flexible scientific research regime.[*5]

Some authors have suggested that to avoid stretching the scientific research regime to an overly wide scope, regulators should specify public interest as a prerequisite for conducting scientific research with health data without the data subject's consent.[*6] 'Public interest' is an undetermined legal term and an ambiguous concept.[*7] There are various theories of public interest in the context of scientific research involving health data.[*8] For example, it has been explained as 'improving a better understanding of underlying mechanisms leading to ill-health or to better options for prevention or treatment'[*9] but also as 'substantial expected advancement of the health-related interests of members of a group whose interests are, or should be, of particular concern to the society in question'.[*10]

Some Member States have explicitly stated in their national laws that scientific research conducted with health data in the absence of the data subject's consent must be in the public interest, while others have not.[*11] This is possible in that the GDPR does not – at least explicitly – require that the scientific research be in the public interest yet does allow Member States to choose their policies.[*12]

The article analyses based on the examples of Estonia and Finland whether national law should require the existence of public interest behind any processing of health data in scientific research without the data subject's consent. This discussion shows that, whether public interest is explicitly required by the legislation or not, in Estonia the requirement exists at least to some extent in connection with mandatory ethics review and in Finland in the data permit procedure. The article also shows that in the future, under the proposed European Health Data Space Regulation[*13] (EHDS), Member States may retain the public interest standard through the ethics review requirement in their national law.

The analysis below begins by examining the GDPR, on which the national laws of Estonia and Finland rely (in Section 2), then delves into the national regulations of Estonia and Finland (in Sections 3 and 4, respectively), before reflection on the change that the EHDS holds potential to bring (in Section 5).

in Georgios Terzis and others (eds), *Disinformation and Digital Media as a Challenge for Democracy* (Intersentia 2020) 348–49. – DOI: https://doi.org/10.1017/9781839700422.020.

3 GDPR (n 1), arts 5 (1)(e), 9 (2)(j), 14 (5)(b), and 17 (3)(d); Evert-Ben van Veen, 'Observational Health Research in Europe: Understanding the General Data Protection Regulation and Underlying Debate' (2018) 104 European Journal of Cancer 70, 72. – DOI: https://doi.org/10.1016/j.ejca.2018.09.032.

4 GDPR (n 1), art 89 (2); van Veen (n 3) 73.

5 Janos Meszaros and Chih-hsing Ho, 'AI Research and Data Protection: Can the Same Rules Apply for Commercial and Academic Research under the GDPR?' (2021) 41 Computer Law & Security Review 105532, 7. – DOI: https://doi.org/10.1016/j.clsr.2021.105532.

6 van Veen (n 3) 76; Janos Meszaros and Chih-hsing Ho, 'Big Data and Scientific Research: The Secondary Use of Personal Data under the Research Exemption in the GDPR' (2018) 59 Hungarian Journal of Legal Studies 4, 403–04; ibid 7–10. – DOI: https://doi.org/10.1556/2052.2018.59.4.5.

7 G Owen Schaefer and others, 'Clarifying How Deploy the Public Interest Criterion in Consent Waivers for Health Data and Tissue Research' (2020) 21 BMC Medical Ethics 23, 2. – DOI: https://doi.org/10.1186/s12910-020-00467-5; Kadriann Ikkonen, 'Avalik huvi kui määratlemata õigusmõiste' [2005](3) Juridica 187.

8 Mark J Taylor and Tess Whitton, 'Public Interest, Health Research and Data Protection Law: Establishing a Legitimate Trade-Off between Individual Control and Research Access to Health Data' (2020) 9 Laws 6, 9–17. – DOI: https://doi.org/10.3390/laws9010006.

9 van Veen (n 3) 76.

10 Schaefer and others (n 7) 4.

11 Fruzsina Molnár-Gábor and others, 'Harmonization after the GDPR? Divergences in the Rules for Genetic and Health Data Sharing in Four Member States and Ways to Overcome Them by EU Measures: Insights from Germany, Greece, Latvia and Sweden' (2022) 84 Seminars in Cancer Biology 271, 275. – DOI: https://doi.org/10.1016/j.semcancer.2021.12.001.

12 GDPR (n 1), arts 9 (2)(j) and 9 (4).

13 Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' COM (2022) 197 final (EHDS Proposal).

## 2. The GDPR's public interest requirement

In one option, the processing of health data for scientific research is possible on the basis of the GDPR's Article 6 (1)(f) (processing is necessary for the purposes of legitimate interests) in combination with Article 9 (2) j) (processing is necessary for scientific research). The data subject's consent is not required unless the EU or the Member State's national law requires it. In addition, as the paper's introduction points out, the GDPR does not require the scientific research in question to be in the public interest.[*14] However, Member States may set a public interest requirement in their national laws, according to Article 9 (2)(j) and 9 (4).

Even though the GDPR does not explicitly impose the condition of the relevant scientific research with health data being in the public interest, one should look at whether the concept of scientific research itself entails the requirement of public interest. While the GDPR does not define scientific research, Recital 159 states that the term should be interpreted in a broad manner that encompasses technological development and demonstration, applied research, and privately funded research. This does not hint at a requirement of public interest. On the other hand, Recital 157 stresses registry-based research's importance for obtaining new knowledge about medical conditions that hold great value and that can aid in improving the quality of life for a number of people. According to Recital 53, scientific research with health data should be based on EU or Member State law, which has to meet an objective of public interest. Relying on these recitals, one might argue that what is deemed processing of health data for scientific research must be in the public interest. However, even though the GDPR recitals refer to some extent to public-interest-linked requirements, they are contradictory and do not have binding legal force.[*15] The body of the GDPR meanwhile does not set any requirement of public interest in connection with scientific research, even though it could have done so in a manner analogous to its addressing of archiving purposes, which explicitly need to be in the public interest according to its Article 9 (2)(j).

The EU institutions have made efforts to clarify the concept of scientific research and its relationship with the public interest. The European Data Protection Board (EDPB) has stated that scientific research in the context of the GDPR means a research project set up in accordance with the relevant sector-related methodology and ethics standards, in conformity with good practice.[*16] The European Data Protection Supervisor (EDPS) has stated, similarly to GDPR recitals 53 and 157, that 'flexibility is afforded on the assumption that research occurring within a framework of ethical oversight serves, in principle, the public interest' and that 'the role of research is understood to provide knowledge that can, in turn, improve the quality of life for a number of people and improve the efficiency of social services'.[*17]

Nonetheless, the opinions of the EU institutions are considered soft-law instruments, the legal force of which is not clear,[*18] and authors of legal literature have interpreted the notion of scientific research in several ways. Ducato has understood scientific research in the GDPR's context as any activity aimed at generating new knowledge and advancing the state of the art in a given field.[*19] Verhenneman is of the view that, even though legal uncertainty remains, scientific research does not necessarily have to serve the public interest, while it still must have value to society.[*20] Slokenberga has been critical of the EDPS's opinion, arguing that it does not adequately consider the complex reality in which scientific research takes place and commercialisation as a means to drive scientific advances forward.[*21]

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14 Ludmila Georgieva and Christopher Kuner, 'Article 9 Processing of Special Categories of Personal Data' in Christopher Kuner and others (eds), *The EU General Data Protection Regulation (GDPR): A Commentary* (OUP 2020) 381. – DOI: https://doi.org/10.1093/oso/9780198826491.003.0038.

15 Case C-162/97 *Nilsson and others* [1998] ECR I-07477, para 54.

16 European Data Protection Board, 'Guidelines 05/2020 on consent under Regulation 2016/679' (version 1.1, adopted on 4 May 2020), para 153.

17 European Data Protection Supervisor, 'A Preliminary Opinion on Data Protection and Scientific Research' (6 January 2020) 2, 11.

18 Santa Slokenberga, 'Setting the Foundations: Individual Rights, Public Interest, Scientific Research and Biobanking' in Santa Slokenberga, Olga Tzortzatou, and Jane Reichel (eds) in *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Cham, Springer 2021) 21. – DOI: https://doi.org/10.1007/978-3-030-49388-2_2; Mart Parind, *Euroopa Liidu õigus. Eesti vaade* (UKU OÜ 2022) 233–38.

19 Ducato (n 2) 3.

20 Griet Verhenneman, *The Patient, Data Protection and Changing Healthcare Models* (Intersentia 2021) 297. – DOI: https://doi.org/10.1017/9781839701252.

21 Slokenberga (n 18) 21.

Therefore, as long as there are no clarifications from the EU legislator or case law of the Court of Justice of the European Union (CJEU), the definition of scientific research remains a grey area.[*22] Bentzen has stated that, by not defining scientific research, the GDPR may extend the privilege it affords to an unintentionally broad range of actors and activities and, unless the term 'scientific research' is clarified, it cannot function as a safeguard against misuse.[*23]

Considering the ambiguity of the concept of scientific research and its relationship with the public interest as articulated in the GDPR, one finds that among the roles of a Member State is to set the standard for 'public interest' in the national law. The following sections illustratively describe how this has been done in Estonia, through mandatory ethics review, and in Finland, via a data permit procedure wherein the criteria for scientific research are assessed. However, as the concept of scientific research should be interpreted autonomously and uniformly throughout the EU,[*24] setting the public interest standard through the national interpretation of scientific research alone is not a solid foundation, in that the future case law of the CJEU may influence national practices.

# 3. Estonia's requirement for a public interest

## 3.1. The public interest requirement in Estonian legislation

The processing of health data for scientific research is regulated by Section 6 of the Estonian Data Protection Act[*25] (EDPA), which is the national law in the meaning of the GDPR's Article 9 (2)(j), Article 9 (4), and Article 6 (1)(e). Even though the explanatory memorandum accompanying the EDPA refers to the last of these three only, it is clear that the EDPA also regulates the processing of health data in the meaning of GDPR Article 9 (2)(j) and makes use of the discretion left to Member States on the basis of the GDPR's Article 9 (4). This interpretation is supported by the explanatory memorandum's references to GDPR Article 89 and Recital 159, which regulate or explain the processing of personal data for scientific research.[*26] Processing of health data for scientific research is possible also on grounds of the GDPR's Article 9 (2)(j) in combination with Article 6 (1)(f), which is unlike the combined application of GDPR Article 9 (2)(j) and GDPR Article 6 (1)(e) in that it does not require the existence of a public interest.[*27]

According to the EDPA's Section 6 (1), health data may be processed without the consent of the data subject for scientific research in a pseudonymised form or a form that provides an equivalent level of protection. Under the same act's Section 6 (3)(2), processing of the data in a form that enables identification of the data subject requires overriding public interest. This requirement for an overriding public interest applies also to the processing of pseudonymised data, according to the Data Protection Inspectorate of Estonia.[*28] An alternative interpretation in the legal literature is that the requirements of Section 6 (3)(2), including the one related to an overriding public interest, apply to the processing of directly identifiable personal data only, excluding pseudonymised data.[*29]

The latter interpretation is in line with the systematic interpretation of the EDPA's Section 6 (2 and 3), from which one can conclude that, in the context of that act's Section 6, the concept of data 'enabling identification of the data subject' does not cover pseudonymised data.[*30] Furthermore, had Section 6 (3)

22 Bentzen (n 2) 349.

23 Ibid 344.

24 Case C-245/00 *SENA* [2003] ECR I-1251, para 23; Parind (n 18) 250.

25 Estonian Data Protection Act (*Isikuandmete kaitse seadus*) adopted on 12 December 2018 (RT I, 4.1.2019 11) (EDPA).

26 Explanatory Memorandum of the Draft of the EDPA (*Seletuskiri isikuandmete kaitse seaduse eelnõu juurde*), 14 <www.riigikogu.ee/download/e0cd5571-165f-46ab-963a-bc69ca08a5da> accessed on 9 February 2023.

27 Data Protection Inspectorate of Estonia, 'Isikuandmed uuringutes' (9 March 2023) <www.aki.ee/et/eraelu-kaitse/isikuandmed-uuringutes> accessed 14 June 2023.

28 E-mail from the Data Protection Inspectorate of Estonia to the author (26 January 2023).

29 Kärt Pormeister, 'Uus isikuandmete kaitse seadus ja isikuandmed teaduses: kolm näidet probleemsest õigusloomest' [2019] (4) Juridica 239, 242; Liisa Maria Kuuskmaa, 'Legal Basis for Processing Personal Data and the Protection of Data Subjects' Rights in Use of Data Concerning Health Collected in the Estonian Health Information System for the Development and Use of Clinical Decision Support Systems' 26 <http://dspace.ut.ee/handle/10062/68545?show=full> accessed 9 February 2023.

30 The EDPA (n 25), s 6 (2) states: 'Depseudonymisation or any other method by which the data not enabling identification of persons are changed again into the data which enable identification of persons', and its s 6 (3) uses the language 'in a format which enables identification of the data subject'.

been meant to extend as far as pseudonymised data, there would have been no need to stress that it applies to data in 'a form which enables identification of the data subject', given the EDPA's coverage of personal data only and not anonymised data. Therefore, it is not clear what kind of data processing must serve an overriding public interest: processing of directly identifiable data only or also pseudonymised data. It seems that the law requires only the processing of directly identifiable data to be in an overriding public interest, rather than pseudonymised data, the latter being much more commonly used in scientific research.

## 3.2. The role of ethics committees in assessing public interest

The EDPA's Section 6 (4) foresees a need for an ethics-committee review in cases of scientific research based on health data. This includes assessing whether there is an overriding public interest in processing health data in a 'form enabling identification of the data subject', however ambiguous the nature of the latter form might be.

Estonia has three widely known active ethics committees in the arena of scientific research that makes secondary use of health data. These are the Estonian Committee on Bioethics and Human Research and two regional committees.*[31] From relying on official communication with the author, it may be concluded that the ethics committees assess the public interest in scientific research or at least its contribution to the common good regardless of the form in which the health data are processed.*[32] At the same time, the ethics committees admit that there is no uniform definition of public interest, and the aims behind each application and the potential results of the proposed efforts need to be assessed on a case-by-case basis.*[33] Among the examples of research in the public interest cited by one of the regional ethics committees is research that enables the enhancement of health policies or more effective treatment, better availability of treatment, or more effective organising of screening.*[34] In contrast, a research project is not in the public interest when the sole object of the activity is to make a profit, with no medically or scientifically new and important knowledge being developed.*[35]

The example of the Estonian Committee on Bioethics and Human Research shows that the ethics review itself includes assessment of public interest in the scientific research context. This is so irrespective of whether there is a requirement of public interest set by law. The tasks of the ethics committee include finding a balance between the protection of fundamental rights and the purposefulness of the research.*[36] No approval will be granted when the research may take pursuing the common good in an irrational direction or when the research does not have scientific value.*[37] Furthermore, the ethics committee relies on the ethics rules that are set for the relevant field(s).*[38] For scientific research involving the secondary use of health data, the WMA Taipei Declaration*[39] is of relevance. One reads under the declaration's point 5 that '[h]ealth research represents a common good that is in the interest of individual patients, as well as the population and the society'. The explication continues with point 8's statement: 'Research and other Health Databases and Biobanks related activities should contribute to the benefit of society, in particular public health objectives.' The tasks and ethics principles described mean that the ethics committee assesses the public interest regardless of whether the law explicitly requires the processing of health data for scientific research to be in the public interest.

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31 The Research Ethics Committee of the National Institute for Health Development and the Research Ethics Committee of the University of Tartu.

32 Per e-mail messages to the author from the Research Ethics Committee of the National Institute for Health Development (of 2 and 5 January 2023), from the Estonian Committee on Bioethics and Human Research (3 January 2023), and from the Research Ethics Committee of the University of Tartu (9 January 2023).

33 Per e-mail from the Research Ethics Committee of the National Institute for Health Development to the author (2 January 2023), from the Research Ethics Committee of the University of Tartu to the author (4 January 2023), and from the Estonian Committee on Bioethics and Human Research to the author (14 February 2023).

34 E-mail from the Research Ethics Committee of the National Institute for Health Development to the author (2 January 2023).

35 E-mail from the Research Ethics Committee of the National Institute for Health Development to the author (4 January 2023).

36 Health Services Organisation Act (*Tervishoiuteenuste korraldamise seadus*) adopted on 9 May 2001 (RT I, 10.10.2022, 4), s $59^4$ (5).

37 Regulations of the Estonian Committee on Bioethics and Human Research (*Eesti bioeetika ja inimuuringute nõukogu kodukord*) adopted on 8 September 2020, para 6.5.3.4 <www.sm.ee/media/2068/download≥ accessed 24 February 2023.

38 Health Services Organisation Act (n 34), s $59^4$ (3).

39 WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks, adopted by the 53rd WMA General Assembly in Washington, DC, in October 2002 and revised by the 67th WMA General Assembly in Taipei, Taiwan, in October 2016.

However, the ethics review may function as a tool for assessing public interest only when the following conditions are met: 1) review is mandatory, 2) all ethics committees follow similar standards, and 3) the committees have sufficient human and financial resources for carrying out the assessment.

Even though, under the EDPA's Section 6 (4), an ethics review is always mandatory in Estonia for health data processing in scientific research that lacks a data subject's consent, the explanatory memorandum on the EDPA gives an impression that no ethics committee approval is required in cases of data held in pseudonymised form.[*40] However, this interpretation is in line with neither the wording of the law nor the understanding of the Estonian Data Protection Inspectorate[*41] and, therefore, should not be relied upon. Although the country has no case law specifying when an ethics review is required, divergence from the wording of the law to the detriment of the data subject in the manner suggested by the explanatory memorandum accompanying the EDPA would not be justified.

Problematically, in Estonia, a researcher may escape the requirement to serve a public interest by applying to an ethics committee that follows looser standards. This is possible because the law does not specifically regulate which ethics committee the researcher intending to process health data has to turn to, except in cases of data requested from the national health information system or the Estonian Biobank. Neither does the law regulate the ethics committees' standards or activities, though there are some exceptions.[*42] Therefore, there should be a framework in place that ensures similar standards for assessing public interest.

A further crucial factor is that ethics committees might not be able to analyse and assess the applications, including the meeting of public interest requirements, in much detail when lacking suitable human and financial resources. A heavy workload and insufficient financial resources have also been recognised as an issue in Estonia.[*43]

### 3.3. Preliminary conclusions from the Estonian setting

The Estonian example shows that assessment of the public interest in scientific research with health data can, in principle, be achieved via mandatory ethics review. This is true notwithstanding whether the law sets a public interest requirement for conducting scientific research with health data. However, this article does not offer any conclusions whether and, if so, to what extent the ethics committees' practice actually encompasses assessing public interest, since in-depth analyses of the committees' decisions are beyond the scope of this paper.

## 4. The public interest requirement in the case of Finland

### 4.1. The public interest requirement in Finnish legislation

In Finland, the secondary use of health data for scientific research is regulated by the Act on the Secondary Use of Social and Health Data[*44] (the Secondary Use Act) and the Finnish Data Protection Act[*45] (the FDPA). According to the Secondary Use Act, the researcher needs a data permit before processing health data for scientific research.[*46] When the data needed are controlled by several public data controllers, the private sector, or Kanta Services[*47], the application for this permit must be submitted to Findata[*48], the national data permit authority for the social and health-care sector. In other cases, the application must be

40 Explanatory Memorandum of the Draft of the EDPA (*Seletuskiri isikuandmete kaitse seaduse eelnõu juurde*), 15 <www.riigikogu.ee/download/e0cd5571-165f-46ab-963a-bc69ca08a5da> accessed on 9 February 2023.

41 Data Protection Inspectorate of Estonia (n 27) as accessed on 14 June 2023.

42 Pormeister (n 29) 248.

43 Siim Espenberg and others, 'Teaduseetika järelevalve ja toetamise riikliku süsteemi loomine Eestis. Lõpparuanne' (2020) 23 <www.etag.ee/wp-content/uploads/2020/01/Teaduseetika-uuringu-l%C3%B5pparuanne_20.01.20-1.pdf> accessed 16 February 2023; ibid 247.

44 The Act on the Secondary Use of Social and Health Data (*Laki sosiaali- ja terveystietojen toissijaisesta käytöstä*) 552/2019 (Secondary Use Act).

45 The Finnish Data Protection Act (*Tietosuojalaki*) 1050/2018 (FDPA).

46 See ss 35 and 38 of the Secondary Use Act (n 44).

47 Kanta produces digital services for the social-welfare and health-care sector. See <www.kanta.fi/en/what-are-kanta-services> accessed 25 January 2023.

48 See 'Finnish Social and Health Data Permit Authority Findata' <findata.fi> accessed 9 February 2023.

submitted to the public body controlling the health data directly.*[49] The discussion here focuses on Findata, the most obviously pertinent entity in the situations at issue.

For Finland, the FDPA's Section 6 repeats the principle stated in the GDPR according to which the ban on processing special categories of data does not apply to scientific research (see §6, point 7). Even though at first sight the Finnish law may give the impression that scientific research needs to be in the public interest, as FDPA Section 4 point 3 refers to GDPR Article 6 (1)(e), which in turn refers to 'tasks carried out in the public interest',*[50] this is not the case. Neither the Secondary Use Act nor the FDPA requires that scientific research be in the public interest. Conducting scientific research is also allowed directly on the basis of legitimate interests; this restriction does not require the processing activity to be in the public interest.*[51]

As noted above with regard to Estonia, a public interest requirement may be derived from mandatory ethics review. However, Finland has no mandatory ethics-review terms similar to Estonia's.*[52] Guidelines, not laws, suggest applying for an ethics review in particular cases wherein the risks arising from use of health registries' data are greater.*[53] Findata's data permit procedure does not judge whether the research project should be submitted for an ethics committee's approval.*[54] Therefore, researchers may gain access to health data without ethics approval. In these circumstances, an ethics-review mechanism cannot function as an effective measure for assessing the public interest in the research.

## 4.2. Interpretation of scientific research in Finnish practice

Despite the lack of public interest or ethics-review requirements in its law, Finland has set a standard for public interest – through the interpretation of 'scientific research' applied in national practice. The criteria that must be met before one obtains access to health data for scientific research purposes have been established in Finnish case law. Dating from 2013, these dictate:

1) an appropriate research plan,
2) sufficient scientific qualifications of the project staff,
3) fulfilling the requirements of autonomy and openness, and
4) the main goals for the study being scientific.*[55]

In the case giving rise to this interpretation, a research company was refused access to health data associated with asthma-related products in the prescription register of the Social Insurance Institution (Kela). The intended research project was funded by a pharmaceutical company, which, problematically, also had the right to comment on the results of the research before publication. In the view of Kela, the entity in the position to decide on granting access to the data, it would not have been possible for such a project to obtain research results that are appropriate in a scientific sense. Kela received the impression that the proposed research was an effort to promote the co-operating pharmaceutical company's sales by publishing a study report that paints a positive picture of that company's products.

The research company's appeal was not successful in court. The court concluded that the possibility of the pharmaceutical company influencing the content of the publications presenting the research had not

49 Secondary Use Act (n 44), s 11.

50 FDPA (n 45), s 4, item 3: 'Personal data may be processed in accordance with point (e) of Article 6(1) of the Data Protection Regulation if: the processing is necessary for scientific or historical research purposes or statistical purposes and it is proportionate to the aim of public interest pursued.'

51 Board presentation HE 9/2018 vp: 'The Government's Proposal to the Parliament as Legislation to Supplement the EU's General Data Protection Regulation', paras 2.3.3 and 2.3.8, per <www.eduskunta.fi/FI/vaski/HallituksenEsitys/Sivut/HE_9+2018.aspx> accessed 9 February 2023; Office of the Data Protection Ombudsman of Finland, 'Scientific Research FAQ', under 'Does scientific research always require consent for the processing of personal data?' <https://tietosuoja.fi/en/faq-scientific-research> accessed 10 January 2023.

52 Iina Kohonen, Arja Kuula-Luumi, and Sanna-Kaisa Spoof (eds), *The Ethical Principles of Research with Human Participants and Ethical Review in the Human Sciences in Finland: Finnish National Board on Research Integrity TENK Guidelines 2019* (2nd edn, TENK 2019) 6 and 19–20.

53 Ibid 6 and 19.

54 E-mail from Findata to the author (17 January 2023).

55 Supreme Administrative Court of Finland Decision KHO:2013:181 22.11.2013/3651; Office of the Data Protection Ombudsman, 'Scientific Research and Data Protection' under 'Characteristics of scientific research' <https://tietosuoja.fi/en/scientific-research-and-data-protection> accessed 10 February 2023; Findata, 'Scientific Research' <https://findata.fi/en/faq/scientific-research/> accessed 11 February 2023; e-mail from Findata to the author (17 January 2023).

been ruled out. The court also found that it could not be concluded with sufficient certainty that the main goals of the research were scientific.*[56]

Therefore, under the notion of 'scientific research', it was not deemed permissible to conduct a study that possibly aimed to promote the commercial interests of one company. Instead, an independent and objective contribution to general scientific knowledge would have been required before access to health data for scientific research could be granted. It can be argued that this condition is a requirement of public interest in the scientific research context.

The above-mentioned case law remains relevant today for both Findata, which considers the scientific research criteria in the course of its data permit procedure, and the data protection authority.*[57] This is true notwithstanding opinions that the GDPR might expand the scope of the Finnish national interpretation of scientific research.*[58]

Finally, it is noteworthy that in Finland innovation and development activities, which often serve commercial interests, are distinguished from 'scientific research', with the former being defined as 'the application and use of technical and business information and existing other information together with personal data when the goal is to develop new or significantly improved products, processes or services'.*[59] For the latter activities, Findata will prepare the relevant datasets and the applicant may obtain access to aggregate-level data only, not to personal data.*[60]

### 4.3. Preliminary conclusions from the Finnish setting

The Finnish example shows that the notion of 'scientific research' may be substantiated on a national level in a way that incorporates public-interest-related requirements such as the criterion of contributing autonomously and objectively to general scientific knowledge. Accordingly, even though the law does not require 'scientific research' to be in the public interest, the public interest is still assessed to some extent in the data permit procedure, wherein the criteria related to scientific research are assessed. Detailed analysis of Findata data permit decisions extends beyond the scope of this article, so no conclusions are drawn here as to the extent to which Findata practice has continued to assess the criteria for 'scientific research'.

## 5. The public interest requirement in the European Health Data Space Regulation proposal

### 5.1. The new framework and the public interest requirement in the EHDS proposal

The proposed EHDS*[61] may change the scope of 'scientific research' and its relationship with the public interest as well as general rules for secondary use of electronic health data. EHDS is meant not to replace the GDPR but to complement it.*[62] Under the instrument as proposed, holders of health data are required to grant access to the health data held to a national central data-access body that coordinates the secondary data use and decides on granting data permits to applicants.*[63] The mechanism resembles the Finnish national Findata system, which was taken as an example in the work to develop the proposal.*[64]

56 Supreme Administrative Court of Finland (n 55).

57 E-mail from Findata to the author (17 January 2023); Office of the Data Protection Ombudsman (n 55).

58 Board presentation HE 9/2018 vp (n 51), para 2.3.8; Tom Southerington, 'Access to Biomedical Research Material and the Right to Data Protection in Finland' in Santa Slokenberga, Olga Tzortzatou, and Jane Reichel (eds) *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Cham, Springer 2021) 254. – DOI: https://doi.org/10.1007/978-3-030-49388-2_13.

59 Secondary Use Act (n 44), s 3, para 4.

60 Ibid, s 37.

61 EHDS Proposal (n 13).

62 Ibid, art 1 (4).

63 Ibid, arts 33, 36, and 46.

64 Commission, 'Commission staff working document impact assessment report accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space' SWD (2022) 131 final, paras 2.2, 2.3, 6.1.1, and 6.1.3.2.

An important change is suggested via Article 34 (1) of the proposal, which extends the list of purposes for which health data may be processed without the data subject's consent*[65] through the inclusion of activities described thus:

(f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
(g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
(h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.

In the proposed EHDS, 'scientific research related to health or care sectors' is listed separately from these activities.*[66] The EHDS proposal does not foresee mandatory ethics review for the intended processing activities or assessment of the qualifications of a data permit applicant's staff.*[67] Interestingly, the EHDS proposal assumes that all of the secondary-use activities under it rely on GDPR Article 9 (2)(h)–(j), without specifying which activity is linked with what legal basis.*[68] Under the GDPR, these activities may be carried out without the data subject's consent principally under the scientific research exemption (per Article 9 (2)(j)) or for reasons of public interest in the field of public health (per Article 9 (2)(i)). Relying on the EHDS proposal, the data user conducting these activities need not demonstrate the legal basis under GDPR Article 9 (2) any longer, but the existence of the legal basis is assumed.*[69] Therefore, under the proposed EHDS, the activities would neither have to meet the criteria set for 'scientific research' nor have to be explicitly in the public interest. That situation would be contrary to the general logic of the GDPR according to which a concrete legal basis stemming from Article 9 (2) is always needed for the processing of health data.

Another possible interpretation addressing the legal basis issue would be that what qualifies as scientific research under the GDPR would become, for example, an innovation and development activity under the EHDS.*[70] However, the proposal does not confirm that interpretation; hence, it creates legal uncertainty. Also, in the case described, the extent to which the relevant innovation and development activity should meet the criteria for scientific research remains unclear, because scientific research has been listed separately from innovation and development activities for the EHDS as proposed.*[71] For clarity and full compliance with the GDPR, the proposal should be amended.

According to Recital 41 of the EHDS proposal, access to data for secondary use should contribute to the general interest of society, yet the standard the proposal sets for 'the general interest of society' remains unclear. Similarly to the GDPR, the proposal does not define scientific research or impose a public interest requirement connected with conducting it. As for the new processing activities listed in Article 34 (1)(f–h), the proposal sets requirements such as 'contributing to public health or social security' or 'ensuring high levels of quality and safety of health care', criteria that are very general. It would probably not be difficult for any applicant to demonstrate an intention to meet them. As the EDPS and EDPB have suggested, the EHDS proposal should circumscribe when there is a sufficient connection with public health or social security, to achieve a balance adequately taking into account the objectives pursued by the proposal and the protection of personal data.*[72] Article 35 of the proposal, which prohibits data processing carried out for the development of products or services that may harm individuals and societies at large, clarifies only the

65 The intended legal bases to which consent is not integral have been explained in the EHDS Proposal's Recital 37.

66 EHDS Proposal (n 13), art 34 (1)(e).

67 Santa Slokenberga, 'Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject That the Proposed EHDS Regulation Promises to Bring Along' [2022] Technology and Regulation 143, 144.

68 EHDS Proposal (n 13), Recital 37.

69 Ibid, Recital 37, arts 45 (4) and 46 (1); Masha Shabani and Sami Yilmaz, 'Lawfulness in Secondary Use of Health Data: Interplay between three Regulatory Frameworks of GDPR, DGA & EHDS' [2022] Technology and Regulation 128, 133; Petros Terzis, 'Compromises and Asymmetries in the European Health Data Space' [2022] European Journal of Health Law 1, 12. – DOI: https://doi.org/10.1163/15718093-bja10099.

70 Santa Slokenberga (n 67) 135, 142.

71 EHDS Proposal (n 13), art 34 (1)(e).

72 EDPB-EDPS, 'Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space' as adopted on 12 July 2022, para 85.

extreme cases wherein the required standard is not met. Therefore, the proposal does not foresee a clear public or general interest standard for the processing of health data.

### 5.2. Member States' discretion in the proposed EHDS system

According to the GDPR's Article 9 (4), Member States may foresee further rules on processing health data, including a public interest requirement for processing health data in scientific research. Under the EHDS proposal, it is questionable whether this will be possible in cases covered by the EHDS. According to the explanatory memorandum on the proposal, the regulation is intended 'to prevent the fragmentation that resulted from inconsistent use of the relevant clauses in the GDPR (e.g. Article 9 (4))'.*[73] In Article 63 of the proposal, it is explicitly stated with regard to the context of international access and transfer of health data that Member States may set further conditions in accordance with GDPR Article 9 (4). A similar provision is not present elsewhere. Therefore, the discretion left to Member States is a matter of some doubt.

Nevertheless, there may be a route for setting a public interest requirement through ethics-review requirements expressed in national laws. According to Article 45 (4) of the proposal, the data permit applicant shall provide 'information on the assessment of ethical aspects of the processing, where applicable and in line with national law'. According to Recital 46, the ethics evaluation should be based on its own merits.

It must be stressed that at the national level ethics approval may typically be required for scientific research only and not for other activities covered by the proposal.*[74] In those conditions, for example, those development and innovation activities that are not considered scientific research do not go through an ethics review. It bears reiterating that under the proposed scheme they also need not meet scientific research criteria or clear standards of public or general interest. In consequence, the data subject's health data might easily get processed without there being fair justification. For setting an appropriate standard for accessing health data, one option is to extend the national law's ethics-review requirements to encompass all activities listed in Article 34 (1)(f–h) of the proposal. In the review mandated, a standard of public or general interest can be employed, with the assessment of compliance being conducted accordingly.

## 6. Conclusion

Analysis shows that, as the GDPR does not assure that the 'scientific research' regime applies in only cases wherein the scientific research is in the public interest, it is up to the Member States to set the relevant public interest standard in their national laws.

The experiences of Estonia and Finland have demonstrated that it is possible to set a public interest standard also without the national legislation explicitly requiring existence of a public interest. The Estonian example illustrates how public interest may be assessed in mandatory ethics review. The Finnish example, in turn, attests that assessing fulfilment of the criteria for 'scientific research' in a national data permit procedure entails evaluating the existence of a public interest to some extent. Therefore, to protect data subjects' right to privacy and self-determination, it is not always necessary to set a requirement of public interest explicitly in legislation. However, with regard to the Finnish case, it must be borne in mind that relying merely on the national interpretation of 'scientific research' which is the autonomous concept of EU law is risky, since future case law of the CJEU might change the way in which Member States have to interpret the notion.

In the future, the proposed EHDS may reduce the discretion of Member States to choose their policies on public interest standards. However, Member States may still retain the public interest standard through an ethics-review requirement imposed by their national law. This should extend equally to scientific research and the other activities listed in Article 34 (1)(f–h) of the proposal, to avoid unintended limitations to the data subject's right to privacy and self-determination.

73 EHDS Proposal (n 13), Explanatory Memorandum, ch 2 ('Choice of the Instrument').

74 Slokenberga (n 67) 144.