European Journal of Risk Regulation (2025), **16**, 228–241
doi:10.1017/err.2024.51

CAMBRIDGE UNIVERSITY PRESS

ARTICLE

Standards for Including Scientific Evidence in Restrictions on Freedom of Movement: The Case of EU Covid Certificates Scheme

Danaja Fabcic Povse and Paul Quinn

Health and Ageing Law Lab, Vrije Universiteit Brussel, Brussel, Belgium
Corresponding author: Danaja Fabcic Povse; Email: danaja.fabcic@gmail.com

Abstract

Compared to previous secondary legislation, Article 11 of the Digital Covid Certificates regulations was remarkably explicit in its requirement for Member States to consider scientific evidence when restricting free movement for the certificate holders. However, we argue in this Article that the regulations achieved a partial codification of the existent case law of the CJEU rather than imposing any additional requirements. Namely, the case law had already required Member States to rely on scientific evidence that reflects the international consensus, that is relevant and up to date, and that the evidence had to demonstrate by means of a risk assessment a real risk to the public health. We also discuss these findings in the light of the proportionality and precautionary principles and suggest that understanding the evolution of the EU legal order's evidentiary requirements is useful in the light of the legislator's claim of objective and rational policy-making procedures in public health and other crises.

Keywords: Covid-19 pandemic; free movement; scientific evidence

I. Introduction

The EU Digital Covid Certificates Scheme, instituted in the summer of 2021 under Regulation 2021/953[1] (the DCCR), and revised in Regulation 2022/1034[2,3], was an initiative to help individuals demonstrate their potentially lower risk concerning the transmission of Covid-19. It had the practical aim of facilitating the reopening of European borders for travel after prolonged closures during the height of the pandemic. The DCCR was therefore a pragmatic and potentially indirect attempt to facilitate freedom of movement between different Member States i.e., one of the pillars of European integration. Whilst neither regulation attempted to decide for Member States what restrictions they could impose on

[1] Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic 2021 (OJ L 211).

[2] Regulation (EU) 2022/1034 of the European Parliament and of the Council of 29 June 2022 amending Regulation (EU) 2021/953 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic 2022 (OJ L 173).

[3] Terminological note. In general, this Article will refer to the DCCR meaning the regulation as it applied until 30 June 2023, unless we explicitly refer to a specific iteration thereof, i.e. DCCR-1 or DCCR-2.

travellers, they explicitly stated (in Article 11) such restrictions should take into account available scientific advice.

Both regulations thus contained an explicit obligation for Member States, unlike the existing laws on the freedom of movement, where the requirement of following available scientific advice has often been seen as implicit. However, in a pandemic characterised by an unknown pathogen on the one hand, and an explicit binding requirement on the other hand, governments would need to take into account rapidly evolving and often conflicting evidence[4] to impose lawful restrictions on travellers. Hence, this paper will ask if stating such a requirement explicitly made any difference. It will also attempt to answer a number of important ambiguities. These include questions such as what type of evidence is acceptable, how it is intertwined with EU legal principles, and how to account for inconclusive or contradictory evidence.

After analysing the provisions of the DCCR in section II, in section III the authors will look at well established EU legal frameworks on the inclusion of scientific evidence. In section IV we will then analyse the approach taken by the DCCR and its apparent consequences or lack thereof.

II. The role of scientific evidence in Article 11 as a substantive obligation for Member States

In this section, we introduce the reader to the two regulations and the wording of Article 11, which will serve as the focal point of our analysis in the subsequent sections.

The DCCR pursued two goals – to enable the use of certificates issued by different Member States across the EU, and to contribute to facilitating the gradual lifting of restrictions to free movement put in place by the Member States after a year and a half of pandemic restrictions.[5] However, while the DCCR dealt with issuance, verification and mutual recognition of Covid certificates, Member States retained full competence over who can be issued a certificate, and where they are required to be shown to gain access. This reflected the EU's limited public health competences as foreseen in the EU treaties.[6] Given this, Article 11 of the DCCR regulations was noteworthy in that it seemingly prevented Member States from imposing any additional restrictions on certificate holders, unless they took into account a number of factors, including scientific advice.[7]

[4] E.g. on the efficacy of masks (which later turned out to be the case), see <https://www.nature.com/articles/d41586-020-02058-1> and <https://www.theguardian.com/commentisfree/2023/mar/23/covid-britain-locked-down-three-years-trauma>; or whether pre-Omicron variants could lead to infection despite vaccination (i.e. a breakthrough infection): <https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/breakthrough-infections-coronavirus-after-vaccination>; or whether travel restrictions could limit the spread: <https://www.cato.org/publications/research-provides-no-basis-pandemic-travel-bans>.

[5] Art 1 of the DCCR

[6] Art 168 of the Treaty on the Functioning of the European Union

[7] Art 11 (DCCR-1)

Restrictions to free movement and information exchange

1. Without prejudice to Member States' competence to impose restrictions on grounds of public health, where Member States accept vaccination certificates, test certificates indicating a negative result or certificates of recovery, they shall refrain from imposing additional restrictions to free movement, such as additional travel-related testing for SARS-CoV-2 infection or travel-related quarantine or self-isolation, unless they are necessary and proportionate for the purpose of safeguarding public health in response to the COVID-19 pandemic, also taking into account available scientific evidence, including epidemiological data published by the ECDC on the basis of Recommendation (EU) 2020/1475.
2. Where a Member State requires, in accordance with Union law, holders of the certificates referred to in Art 3(1) to undergo, after entry into its territory, quarantine or self-isolation or to be tested for SARS-CoV-2 infection, or if it imposes other restrictions on the holders of such certificates because,

1. Conditions for further restrictions

According to the DCCR, Member States were only allowed to create future restrictions on individuals insofar they were "necessary and proportionate" to limit the spread of the pandemic. Member States were also required to "take into account available scientific evidence, including epidemiological data published by the ECDC."[8] According to Article 11(2), an emergency brake procedure was allowed for Member States when for example the epidemiological situation worsened quickly, especially due to the emergence of a variant of concern or interest. If Member States were to decide to impose additional restrictions, they had to inform the Commission as well as other Member States within 48 hours about the reasons, the scope and the duration of such measures.

Article 11(4) further obliged Member States to provide the public with clear, comprehensive and timely information on restrictions, in principle at least 24 hours before they came into effect. Moreover, the information provided was to be made publicly available by the Commission in a centralised manner.[9]

The revised Article 11 in the DCCR-2[10] specified that any additional restrictions upon certificate holders could only be imposed insofar they were "non-discriminatory, and

for example, the epidemiological situation in a Member State or in a region within a Member State worsens quickly, in particular as a result of a SARS-CoV-2 variant of concern or interest, it shall inform the Commission and the other Member States accordingly, if possible 48 hours in advance of the introduction of such new restrictions. To that end, the Member State shall provide the following information:

(a) the reasons for such restrictions;
(b) the scope of such restrictions, specifying which certificate holders are subject to or exempt from such restrictions;
(c) the date and duration of such restrictions.

3. Member States shall inform the Commission and the other Member States of the issuance and the conditions of acceptance of the certificates referred to in Art 3(1), including the COVID-19 vaccines they accept pursuant to the second subparagraph of Art 5(5).
4. Member States shall provide the public with clear, comprehensive and timely information with regard to paragraphs 2 and 3. As a general rule, Member States shall make that information publicly available 24 hours before new restrictions come into effect, taking into account that some flexibility is required for epidemiological emergencies. In addition, the information provided by the Member States may be made publicly available by the Commission in a centralised manner.

[8] The EDCD produced such data on the basis of Recommendation (EU) 2020/1475 (Art 11(1)).

[9] For example, the Reopen-EU platform: <https://reopen.europa.eu>, which also provides historical data on movement restrictions.

[10] Art 11 (DCCR-2)

Restrictions to free movement and information exchange

1. Without prejudice to Member States' competence to impose restrictions to free movement on grounds of public health, where Member States accept vaccination certificates, test certificates indicating a negative result or certificates of recovery, they shall refrain from imposing additional restrictions to free movement, unless such restrictions are non-discriminatory, and necessary and proportionate for the purpose of safeguarding public health based on the latest available scientific evidence, including epidemiological data published by the ECDC on the basis of Council Recommendation (EU) 2022/107 (1), and in line with the precautionary principle.
2. Where a Member State imposes, in accordance with Union law, including the principles set out in paragraph 1 of this Art, additional restrictions on holders of the certificates referred to in Art 3(1), in particular as a result of a SARS-CoV-2 variant of concern or interest, it shall inform the Commission and the other Member States accordingly, if possible 48 hours in advance of the introduction of such new restrictions. To that end, the Member State shall provide the following information:
   (a) the reasons for such restrictions, including all relevant epidemiological data and scientific evidence supporting those restrictions that are available and accessible at that stage;
   (b) the scope of such restrictions, specifying which certificate holders are subject to or exempt from such restrictions;
   (c) the date and duration of such restrictions.

necessary and proportionate for the purpose of safeguarding public health based on the latest available scientific evidence, including epidemiological data published by the ECDC on the basis of Council Recommendation (EU) 2022/107, and in line with the precautionary principle" (Article 11(1) of the DCCR-2). Further, it added in the second paragraph that measures could be imposed in particular as a result of a Covid variant of concern or interest (Article 11(2) of the DCCR-2). Finally, the new paragraph 2a specified that if a member state imposed such restrictions, it had to pay particular attention to the likely impact of such restrictions on cross-border regions, outermost regions, exclaves, and geographically isolated areas (Article 11(2a) of the DCCR-2). The final two paragraphs were identical to the DCCR-1.

2. *What constituted scientific evidence for the purposes of the regulation?*

Article 11 referred to the epidemiological data published by the ECDC on the basis of Recommendation (EU) 2020/1475.[11] Under this recommendation, a "traffic lights" system was set up, alongside common thresholds which Member States could take into account when designating restrictions on freedom of movement. The green, or otherwise, status of a member state was based upon three data points (Covid notification rate, test positivity rate and testing rate), collected nationally and regionally, which would be evaluated by the ECDC. In turn, the ECDC's role was to provide data on the population size, the hospitalisation rate, the rate of ICU admission and the mortality rate, and provide colour-coded weekly maps.[12] However, the provision of Article 11 did not only require Member States to consider the data published by the ECDC, but to take into account "scientific evidence". The use of the word "including" suggests that Members States could (or should?) consider a range of scientific evidence that goes beyond the opinions of the ECDC. Despite this, the Regulations remained unclear as to what type of evidence could or should have been considered. Scientific evidence can refer to peer reviewed journal Articles, opinions of health authorities, or more procedural aspects, such as involving advisors in the policy making process or its monitoring, or anything in between. It wasn't clear either what field of science the evidence could be drawn from – natural sciences, social sciences, public health ethics etc., though a strict definition would perhaps have been considered too limiting. As a result, whilst Article 11 of the DCCR regulation clearly and explicitly called for the consideration of scientific advice, it offered little in terms of clarity for how such advice should be constituted beyond the use of data provided by the ECDC. Nor did it suggest what weight such advice should be given in comparison to other factors. We discuss the nature of scientific evidence further in section III from the perspective of the existing legal frameworks.

2a. Where a Member State imposes restrictions in accordance with paragraphs 1 and 2, it shall pay particular attention to the likely impact of such restrictions on cross-border regions and to the specificities of outermost regions, exclaves and geographically isolated areas.

3. Member States shall inform the Commission and the other Member States of the issuance and the conditions of acceptance of the certificates referred to in Art 3(1), including the COVID-19 vaccines they accept pursuant to the second subparagraph of Art 5(5).

4. Member States shall provide the public with clear, comprehensive and timely information with regard to paragraphs 1, 2 and 3. As a general rule, Member States shall make that information publicly available 24 hours before new restrictions come into effect, taking into account that some flexibility is required for epidemiological emergencies. In addition, the information provided by the Member States may be made publicly available by the Commission in a centralised manner.

[11] Recommendation 2020/1475 - Coordinated approach to the restriction of free movement in response to the COVID-19 pandemic 2020 (L 337/3).

[12] Due to very low testing rates, the map does not seem to be updated any more, however, historical data is available at <https://www.ecdc.europa.eu/en/covid-19/country-overviews>.

3. Proportionality requirement

Recital 14 of the DCCR stated that the certificates' role was to facilitate the application of the principles of proportionality and non-discrimination with regard to restrictions to free movement during the Covid-19 pandemic, while pursuing a high level of public health protection.

Accordingly, Article 11 required Member States to consider the proportionality of further restrictions placed on certificate holders.[13] This followed concerns raised by numerous voices on the proportionality of Covid-19 measures, from the early lockdowns and restrictions[14] and the introduction of certification,[15] particularly regarding their impact on vulnerable groups.[16] Given that scientific advice must often be weighed against other policy considerations, including those related to socio-economic interests, and individual liberties, the concept of proportionality can be used to weigh such differing societal and individual interests. Nevertheless, despite the pertinence of such advice, it is still up to the policy makers concerned to decide when the proportionality test has been met. It is not possible to say in an abstract manner to say when policy makers should be persuaded by scientific advice that restrictive measures may be necessary, and when it may be considered proportional to infringe upon the rights of individuals, groups, or communities in society. Ultimately, policy makers must make such decisions on a case-by-case basis in deciding whether to follow scientific advice and to what degree, allowing them at the same time greater flexibility, at the possible risk of legal foreseeability.[17]

4. The inclusion of precautionary principle in the second Regulation

The second DCCR regulation, unlike the first one, explicitly required Member States to respect the precautionary principle when adopting additional restrictions for pass holders (cf. Article 11 and Recital 13 of the DCCR-2). According to the revised Article 11 in the DCCR-2, Member States had to apply additional restrictions in accordance with the precautionary principle. However, as will be discussed *infra*, the Court in some cases already considered the precautionary principle to be a binding requirement on Member States when dealing with uncertain evidence in public health crises. Nevertheless, the reasons for its inclusion in the second regulation, but not the first, remain unclear, considering that by then far more was known about the transmission and immunity surrounding Covid-19.

[13] Proportionality was explicitly mentioned in rec. 14 of the DCCR, which stated that the certificates' role was to facilitate the application of the principles of proportionality and non-discrimination with regard to restrictions to free movement during the Covid-19 pandemic, while pursuing a high level of public health protection.

[14] I Goldner Lang, "'Laws of Fear' in the EU: The Precautionary Principle and Public Health Restrictions to Free Movement of Persons in the Time of COVID-19" (2021) European Journal of Risk Regulation 1.

[15] E Paris, "Applying the Proportionality Principle to COVID-19 Certificates" (2021) 12 European Journal of Risk Regulation 287.

[16] BN Kumar and others, "Reducing the Impact of the Coronavirus on Disadvantaged Migrants and Ethnic Minorities" (2021) 31 European Journal of Public Health iv9.

[17] In the *Roos* and *Nordic Info* cases, the Court stated that proportionality of the measure must be evaluated in the light of the scientific evidence as existing at the time of the decision. This is especially relevant in a pandemic situation, where evidence is gradually discovered, with new findings challenging or confirming the existing body of knowledge. *Robert Roos and Others v European Parliament* (2022) GC Joined Cases T-710/21 and T-722/21 (212); *Nordic Info BV v Belgische Staat* (2023) ECJ C-128/22 (90).

III. The role of scientific evidence in shaping evidentiary requirements in the EU free movement law

In this section, we embed the issues at stake in Article 11 within the EU legal regime – evidentiary requirements permitting exceptions from free movement as part of the risk regulation framework. Even though the DCCR was adopted on the basis of the non-discrimination clause of Article 21(2) TFEU,[18] the authors of this paper would argue that its main *de facto* purpose was to facilitate freedom of movement, hence its relevance to this framework. This is supported not only by the regulation's name, but also by the contents of Article 1, which states:[19]

> "This Regulation lays down a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic. This Regulation shall also contribute to facilitating the gradual lifting of restrictions to free movement put in place by the Member States, in accordance with Union law, to limit the spread of SARS-CoV-2, in a coordinated manner."

The authors will examine the role of scientific advice as a justification for Member States when they restrict free movement, as well as its interaction with EU legal principles and its nature as a legal requirement. This will in turn build a framework to analyse the effects of Article 11 *infra*.

1. Scientific evidence and justifying exceptions to free movement

Initially, EU law, including case-law, sought to *remove barriers* to trade, while later it shifted toward *regulating risks* to ensure the functionality of the internal market. Later, spillover effects of different national regimes led to an increasingly important role for risk regulation, which includes a scientific assessment dimension, as shaped by the Court's jurisprudence.[20] Briefly put, scientific evidence plays a key role in justifying the Member State's departure from the norms of the internal market by relying on the permissible exceptions to free movement. Such exceptions can also be found in the treaties, as well as secondary law, and inter alia allow for restrictions for reasons of public health, including to fight an epidemic disease (for example, Article 29 of the Free Movement Directive[21]), though the legislator lagged behind the Court due to institutional barriers.[22]

[18] Art 21(2) TFEU: Every citizen of the Union shall have the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give them effect.

[19] Furthermore, in case of conflict between citizenship and free movement provisions, the latter take precedence. Cf. *S v Minister voor Immigratie, Integratie en Asiel and Minister voor Immigratie, Integratie en Asiel v G* (2014) ECJ Case C-457/12 (45).

[20] A Alemanno, "The Shaping of European Risk Regulation by Community Courts" (SSRN Scholarly Paper, 1 January 2009) <https://papers.ssrn.com/abstract=1325770> (last accessed 17 April 2024).

[21] Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (Text with EEA relevance) 2004 (OJ L 158).

[22] Alemanno (n 20).

In case-law, scientific evidence has been used to justify various actions, ranging from denial of treatment,[23] the marketing ban on fortified foodstuffs[24] such as cereals,[25] selling alcoholic drinks with additives,[26] to defence in criminal proceedings,[27] with varying levels of success. To pass the test, the Member States must prove that their actions were based on a risk assessment, which in turn relied on valid, recent evidence, showing a *concrete risk* to public health instead of a vague, potential danger.

a. The nature of scientific evidence

The Court has attempted to define the required level of scientific evidence a number of times. It has been described as what is "considered normal" according to (scientific) standards,[28] and has been "sufficiently tried and tested,"[29] while containing all the relevant and latest available information. Moreover, the evidence must have been produced by international scientific research,[30] and in case of conflict between the national and international consensus, only the latter is seen as acceptable by the Court.[31] Finally, taking into account the evolving nature of scientific research, the evidence that the restriction relies on is the evidence known when the measures are adopted.[32]

However, what is not clear is the type of evidence that Member States can refer to. Unlike in public health sciences, with its clear hierarchy of the evidence pyramid (topped by the (meta)systematic reviews, and randomised controlled trials, though that too has been criticised by the scientific community), the Court does not clearly state what exactly constitutes evidence. Given that policymakers are not scientists, and that when relevant, they largely rely on advisors rather than the evidence itself, the case-law is relatively sparse. As examples of required evidence, the Court has suggested that the Member States should consult "existing scientific literature and studies, [and] the authorised opinions of specialists."[33] Nevertheless, where advisory groups on EU level exist, the Member States must also take their work into account, such as the EU's scientific committee for food,[34] or during the Covid-19 pandemic, the ECDC.[35,36]

b. Evidence demonstrating a specific, concrete risk to public health

The restriction cannot be justified unless there is a concrete risk to public health (i.e., no blanket prohibitions). As stated in the Beer Purity case, which consolidated earlier case-law, "[m]ere reference to the potential risks … does not suffice to justify the imposition

[23] *BSM Geraets-Smits v Stichting Ziekenfonds VGZ and HTM Peerbooms v Stichting CZ Groep Zorgverzekeringen* (2001) Court of Justice of the European Union C-157/99.

[24] *Criminal proceedings against Sandoz BV* (1983) ECJ Case 174/82.

[25] *Commission of the European Communities v Kingdom of the Netherlands (Vitamins)* (2004) Court of Justice of the European Union C-41/02.

[26] *Commission of the European Communities v Federal Republic of Germany (Purity requirements for beer)* (1987) ECJ Case 178/84.

[27] *Criminal proceedings against B S and C A* (2020) ECJ Case C-663/18.

[28] *BSM Geraets-Smits v Stichting Ziekenfonds VGZ and HTM Peerbooms v Stichting CZ Groep Zorgverzekeringen* (n 23) para 94.

[29] Ibid.

[30] *Vitamins* (n 25) para 49; *Criminal proceedings against B S and C A* (n 27) paras 87 and 91.

[31] *BSM Geraets-Smits v Stichting Ziekenfonds VGZ and HTM Peerbooms v Stichting CZ Groep Zorgverzekeringen* (n 23).

[32] *Nordic Info BV v Belgische Staat* (n 17).

[33] *BSM Geraets-Smits v Stichting Ziekenfonds VGZ and HTM Peerbooms v Stichting CZ Groep Zorgverzekeringen* (n 23) para 98.

[34] *Criminal proceedings against Sandoz BV* (n 24) para 17.

[35] *Nordic Info BV v Belgische Staat* (n 17) paras 85 and 91.

[36] This approach was similarly followed in the Art 11 requirement to consider the epidemiological data published by the ECDC.

of stricter rules",[37] and the risks involved must be specifically demonstrated – restrictions require a "concrete justification", in the words of the Court.[38] This approach was followed in *Vitamins* (*Commission v. Netherlands*),[39] where the Court required that the respondent government should have produced a risk assessment, identifying potential negative consequences, based on internationally recognised scientific evidence demonstrating the risk to public health (i.e., risks presented by the fortification of foodstuffs by additional vitamins).[40] The need for Member States to carry out risk assessments was confirmed in *Greenham and Abel*,[41] where the Court reiterated that refusing to authorise marketing of foodstuffs "must be based on a detailed assessment of the risk to public health."[42]

2. The role of precautionary and proportionality principles

The Court acknowledges that measures and policies rely on other interests beyond scientific evidence, avoiding a purely technocratic assessment by taking into account legitimate societal interests, including managing uncertainty. This can be necessary because different actors will have different risk perceptions, and although relying on science can increase the legitimacy of processes,[43] science alone is not determinative in guiding decision-making, let alone making value-based (court) judgments.[44] This may help explain the Court's frequent reliance on the principles of proportionality and precaution in such cases.

The proportionality principle, which does not require particular methods or measures, allows for Member State flexibility in their responses to public health crises, though in the Covid-19 pandemic its application was rendered more difficult due to the high level of uncertainty surrounding a novel pathogen.[45]

In EU public health law, the proportionality test usually consists of two criteria:[46] suitability (does the measure objectively lead to the goal) and necessity (is there a less restrictive measure still leading to the same goal).[47] This means that the court will consider the costs and benefits of the public health measure against protected interests in order to evaluate its lawfulness, with less room for societal interests compared to a three-step test.[48]

[37] *Beer purity* (n 26) para 49.

[38] Ibid 47.

[39] *Vitamins* (n 25).

[40] Ibid 53.

[41] *Criminal proceedings against John Greenham and Léonard Abel* (2004) ECJ C-95/01.

[42] Unlike in *Vitamins*, however, it did not consult the contents of the risk assessment, restricting itself to a purely procedural check.

[43] J Peel (ed), "Case Studies of Science and Risk Regulation in International Law" in *Science and Risk Regulation in International Law* (Cambridge University Press 2010) <https://www.cambridge.org/core/books/science-and-risk-regulation-in-international-law/case-studies-of-science-and-risk-regulation-in-international-law/C4078F541D3120D50065B753EE9E067C> (last accessed 26 April 2021).

[44] G Davies, "Does Evidence-Based EU Law Survive the Covid-19 Pandemic? Considering the Status in EU Law of Lockdown Measures Which Affect Free Movement" (2020) 2 Frontiers in Human Dynamics. <https://www.frontiersin.org/article/10.3389/fhumd.2020.584486> (last accessed 17 January 2022).

[45] Goldner Lang (n 14).

[46] Leaving out the proportionality *sensu stricto*. However, there are some exceptions – e.g. in *Roos* and *Nordic Info* the court also evaluated proportionality *sensu stricto*, returning to the "classic" proportionality test to account for wider societal aspects (cf. point 123 of the AG's opinion in *Nordic Info*).

[47] Goldner Lang (n 14) 18–19; *Opinion of Mr Advocate General Poiares Maduro delivered on 13 July 2006 Criminal proceedings against Jan-Erik Anders Ahokainen and Mati Leppik* (2006) Court of Justice of the European Union C-434/04.

[48] See for example Peel (n 42). Decisions based on purely scientific advice are rare aside from some very narrow technocratic areas; instead, a mix of a political and scientific assessment will take place.

However, in its first pandemic case, *Nordic Info*, it did apply the third part of the test as well, stating that measures need to properly balance the pursued objective, and "the rights and principles at issue, in order to ensure that the disadvantages caused by that measure are not disproportionate to the aims pursued."[49] In this way, the Court seems to be revising its two-step assessment in public health cases in favour of the usual, three-step test.[50]

Precaution, on the other hand, has long been associated with managing risks when faced with uncertain scientific evidence. Associated with risk governance, assessment and communication,[51] it was originally developed as a means of mitigating possible impacts of innovation, and experienced a revival during the pandemic.[52] The principle is, however, not an anti-catastrophe principle, but rather a means to address critical risks in a situation of incomplete information (the so-called irreversibility problem).[53] In the CJEU's case-law, the principle has likewise been recognised as a way to account for scientific uncertainty (cf. *Vitamins*[54]), and permitting Member States to impose protective, *ex ante* restrictions "without having to wait until the existence and gravity of those risks become fully apparent."[55]

During the pandemic, many of the measures adopted by Member States were precautionary in their nature. In *Nordic Info*,[56] the Court reiterated that precautionary measures such as masking obligations, testing and quarantines, which aimed to limit the spread of the pandemic, can be permissible under free movement law, insofar alternative measures (such as a travel ban) would not have been as effective.[57,58] However, the Court also hinted that the precautionary character of pandemic measures might make it more difficult to establish proportionality in such cases, which suggests a more complex relationship between the two principles than previously understood.[59]

3. *The role of ECDC in harmonising restrictions*

Compared to the CDC in the US, the ECDC has played a less active role in the pandemic. The reasons can be found in its competence limitations (pursuant to Article 168 of the TFEU,

[49] *Nordic Info BV v Belgische Staat* (n 17) para 93.

[50] We could speculate that the Court followed the AG's reasoning in that the first two steps are "efficiency" focused, and in a pandemic with major socio-economic, health and other consequences, believing that those need to be accounted for, rather than going for a purely technocratic, science-based approach.

[51] European Parliamentary Research Service, "The Precautionary Principle. Definitions, Applications and Governance" (European Parliamentary Research Service 2015) <https://www.europarl.europa.eu/RegData/etudes/IDAN/2015/573876/EPRS_IDA(2015)573876_EN.pdf>.

[52] CR Sunstein, "This Time the Numbers Show We Can't Be Too Careful" (*BQ Prime*) <https://www.bqprime.com/view/coronavirus-lockdowns-look-smart-under-cost-benefit-scrutiny> (last accessed 14 July 2023).

[53] CR Sunstein (ed), "Reconstructing the Precautionary Principle — and Managing Fear", *Laws of Fear: Beyond the Precautionary Principle* (Cambridge University Press 2005) <https://www.cambridge.org/core/books/laws-of-fear/reconstructing-the-precautionary-principle-and-managing-fear/6B6BF2D88139AA1FCD2E934EE3CAAA65> (last accessed 26 April 2021).

[54] *Vitamins* (n 25) paras 43–44.

[55] Ibid 52.

[56] *Nordic Info BV v Belgische Staat* (n 17).

[57] Ibid 90.

[58] It is noteworthy that travel bans are usually not considered an effective measure to limit the spread of a pandemic, see GM Vergallo and others, "Does the EU COVID Digital Certificate Strike a Reasonable Balance between Mobility Needs and Public Health?" (2021) 57 Medicina 1077; "Research Provides No Basis for Pandemic Travel Bans" (*Cato Institute*, 15 April 2020) <https://www.cato.org/publications/research-provides-no-basis-pandemic-travel-bans> (last accessed 18 January 2024); SXW Gwee and others, "Impact of Travel Ban Implementation on COVID-19 Spread in Singapore, Taiwan, Hong Kong and South Korea during the Early Phase of the Pandemic: A Comparative Study" (2021) 21 BMC Infectious Diseases 1.

[59] *Nordic Info BV v Belgische Staat* (n 17) para 97.

Member States retain most competences over public health matters), which are further limited by the Meroni doctrine, and its lack of funding and staff.[60]

However, despite these restrictions, the EU's "work in progress"[61] pandemic response framework has enabled the ECDC to play a role as well, giving the Regulation (EC) no 851/2004[62] the mandate to identify, assess and communicate current and emerging threats to human health from communicable diseases. From late 2020 onward (i.e., during the second wave, just before the vaccines were developed), the ECDC collected data based on which common (if non-binding) criteria could be adopted to guide Member States in adopting restrictions; later, it was turned into the "traffic lights" system that displayed the relative risks per area concerned.[63] The explicit reference to the ECDC's data collection in Article 11 of the DCCR is interesting in this regard, as it turns a previously non-binding recommendations system into a binding requirement for Member States, albeit in a narrow area. We will discuss the implications of that *infra*, in section IV.

In order to ensure the ECDC can play a more effective role in future public health crises, it would need to obtain additional funding and staff, the prevention and early warning systems will require more coordination, as well as more consistent data sharing.[64] A new ECDC regulation[65] has been adopted and might answer some of those challenges in the future.

4. *Scientific evidence as a procedural and substantive requirement*

It is apparent from the rich case-law that the Court does more than just look at the existence of scientific evidence during a decision-making process (procedural review), it also evaluates its relevance and gives it legal value (substantive review). This is a departure from the Court's procedural review when reviewing the action taken by the *European* legislator, as opposed to the *national* one when transposing or enforcing EU law.[66] In this sense, the limited procedural requirements outlined in Article 11 of the DCCR regulation (i.e., to seek advice inter alia from the ECDC) seem to be a novelty. However, it remains an arguably weak requirement, as it appears non-exclusive and is not indicative of which other sources of scientific advice should be sought. Nor is the DCCR very instructive in terms of providing a substantial standard beyond the inclusion of the requirements of necessity and proportionality (and later precaution) – though as outlined, the case-law is rich on substantive aspects of what type of evidence can be offered as a justification for movement restrictions (see above in section A.1). How the existent case-law guided the interpretation of Article 11 of the DCCR will be discussed in the next section.

IV. Interpreting the role of Article 11

In this section, we interpret Article 11 in light of the above considerations, and determine whether it worked as an attempt at codification (harmonisation) in a narrow area, or

[60] J Jordana and JC Triviño-Salazar, "Where Are the ECDC and the EU-Wide Responses in the COVID-19 Pandemic?" (2020) 395 The Lancet 1611.

[61] A Renda and R Castro, "Towards Stronger EU Governance of Health Threats after the COVID-19 Pandemic" (2020) 11 European Journal of Risk Regulation 273.

[62] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control 2004 (OJ L).

[63] The map has been taken down as of late 2023, and is now incorporated in the ERVISS system <https://www.ecdc.europa.eu/en/publications-data/european-respiratory-virus-surveillance-summary-erviss>.

[64] Renda and Castro (n 60).

[65] Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control 2022 (OJ L).

[66] See more for an in-depth analysis: K Lenaerts, "The European Court of Justice and Process-Oriented Review" (2012) 31 Yearbook of European Law 3.

whether it produced additional obligations on Member States, which in turn helps us evaluate whether an explicit obligation for Member States made a difference in view of the existing legal frameworks.

1. Codifications and inconsistencies

Following the case-law, the DCCR codified a number of existing requirements, such as the adherence to principles of proportionality, and precaution (albeit only in the second regulation), and the need to observe the latest available scientific evidence. Other requirements, such as the need to carry out a risk assessment, what exactly constitutes evidence outside the "latest available" element, or that the evidence must reflect the international consensus, were not codified in the Article. The inclusion of the precautionary principle in the second, but not the first regulation, is likewise puzzling.

These requirements would have remained binding as part of the consolidated case-law, but the reason for their omission is unclear. *Infra*, we consider the implications of the omitted requirements.

a. Risk assessment

The omission of this requirement within the DCCR regulation is puzzling given that risk assessments are useful in such cases since they bring together scientific evidence and policy responses.[67] An explicit requirement in Article 11 could arguably have obliged Member States to clarify their measures more clearly, demonstrating why they were needed to limit the spread of the pandemic.[68]

b. What is evidence?

In its case-law the Court has consistently asked for *all* the relevant available information. The reference to the ECDC within Article 11 was notably much narrower in scope. The pandemic was noteworthy for the sheer breadth of possible sources of information, particularly in its later stages. Indeed, critiques of policy were often made on the basis that policymakers considered advice that was too narrow in scope, for example advice that did not consider the variety of scientific disciplines (ranging from the psychological to the socio-economic),[69] since not only biomedical sciences, but social sciences and humanities as well can all meaningfully contribute to an appropriate public health response.[70]

Some further guidance may arguably be found in the non-binding road map documents the Commission produced in order to guide Member States. In the first document, the Commission stated that Member State action should rely on science to protect public health. According to the Roadmap, measures should rely on "available scientific evidence,"

[67] Peel (n 42); Goldner Lang (n 14); Alemanno (n 20).

[68] Instead of citing vague political goals, as per M McKee, "If We Are No Longer 'Following the Science,' What Are We Following?" (2022) 377 BMJ o930.

[69] M McKee, "Beyond 'Following the Science': Value Judgements and Transparency in Pandemic Decision-Making" (*UK Pandemic Ethics Accelerator*, 10 November 2022) <https://ukpandemicethics.org/blog/martin-mckee-beyond-following-the-science-value-judgements-and-transparency-in-pandemic-decision-making/> (last accessed 10 November 2022).

[70] See e.g. multidisciplinary works of (inter alia) L Nurgalieva and others, "Public Views on Digital COVID-19 Certificates: A Mixed Methods User Study" in *Proceedings of the 2022 CHI Conference on Human Factors in Computing Systems* (Association for Computing Machinery 2022). https://doi.org/10.1145/3491102.3502066 (last accessed 8 September 2022); D Goldberg, "When Crafting Public Health Policy, the Perfect Shouldn't Be the Enemy of the Good" (*Bill of Health*, 9 March 2023) <https://blog.petrieflom.law.harvard.edu/2023/03/09/when-crafting-public-health-policy-the-perfect-shouldnt-be-the-enemy-of-the-good/> (last accessed 10 March 2023); JV Lazarus and others, "A Multinational Delphi Consensus to End the COVID-19 Public Health Threat" (2022) 611 Nature 332.

and be revised "as more scientific evidence appears".[71] In the second "re-opening roadmap" (A Common Path to Safe and Sustained Re-opening), released alongside the DCCR proposal in March 2021,[72] the Commission favoured a proactive response as opposed to a reactive one. In it, the Commission stated that reopening measures should be supported by scientific evidence, and should be based on robust epidemiological indicators, respecting the proportionality principle. In other words, relaxations would occur when the virus was under control, and the restrictions should not last longer than necessary. In the concluding section of the document, the Commission described its way forward by means of coordinated action, scientific basis, and the health union to guide the decision-making. Whilst perhaps being instructive as to what the EU Commission considered good practice, the non-binding document cannot be considered to provide either legal authority or guidance.

The authors of this paper would submit that attempting to define what the international consensus was, in a period of scientific uncertainty and proliferation of Covid-19 research, would not have been feasible,[73] though it is nonetheless noticeable that the regulation only makes reference to the ECDC as an *explicit* source of evidence, without mentioning either the guidelines or referring to the existing case-law.

c. *International character of evidence*

Furthermore, the provision is silent on the need to consult the evidence that reflects the *international*, not the national (or European?) consensus. The authors would suggest that the reference to the ECDC implies that the legislator saw its work as capable of representing the international consensus. While the ECDC's mandate is European and not truly international in nature, as an organisation it would (especially during the pandemic) be able to evaluate the current consensus in the global scientific community.[74] However, an explicit requirement in Article 11 would have led to more clarity on whether the legislator meant to follow the case-law, or impose its own vision of the international character of evidence.

d. *Inconsistent codification of the precautionary principle*

The DCCR was adopted while the underlying scientific evidence on immunity and transmission of Covid-19 was still uncertain. Interestingly, only the second iteration of the regulation explicitly included the principle, while the first one only referred to it in the recitals. The reason for its omission is not clear, as neither the first proposal nor any of the later preparatory works mention it, until it appears in the text of the second proposal.

We can speculate that the principle was initially omitted due to its vague nature rendering it inoperable in a pandemic situation, as some authors have stated.[75] Nevertheless, the DCCR's initial silence on the precautionary principle does not mean that Member States did not need to respect it, as it remains a requirement of case law.

[71] Joint European Roadmap towards lifting COVID-19 containment measures 2020 (2020/C 126/01) 5.

[72] Communication from the Commission to the European Parliament, the European Council and the Council. A common path to safe and sustained re-opening 2021 (COM).

[73] To illustrate the sheer number of (recent!) studies, we used the query "covid-19" and filters "since 2023" and "sort by date" in Google Scholar, which returned more than 350.000 results. <https://scholar.google.com/scholar?hl=en&as_sdt=0,5&q=%22covid-19%22&scisbd=1>

[74] In fact, in terms of the European response, the ECDC, alongside the Health Security Committee, appears to have played a key role despite limited competences, by inter alia allowing the Union to coordinate national action and gather information centrally – cf. Renda and Castro (n 60); T Deruelle and I Engeli, "The COVID-19 Crisis and the Rise of the European Centre for Disease Prevention and Control (ECDC)" (2021) 44 West European Politics 1376.

[75] A Nordgren, "Pandemics and the Precautionary Principle: An Analysis Taking the Swedish Corona Commission's Report as a Point of Departure" (2023) 26 Medicine, Health Care, and Philosophy 163.

Rather, its inclusion in the second regulation confirms the DCCR's nature as a partial codification of the existing requirements.

2. *Data collected by the ECDC as a harmonising element*

As discussed *supra*, the provision of Article 11 also gave legal effect to the ECDC's collection of data on Covid-19 (case notification rates, test positivity rates, and test rates), resulting in the "traffic lights" system.

Prior to the explicit inclusion in the Article, the data collected by the ECDC would have been used for issuing recommendations. Effectively, this gave the ECDC an indirect power to shape the movement restrictions on an EU-wide level; even though its role was still far from that played by the CDC in the United States,[76] its inclusion was consistent with the case-law, which had previously acknowledged the work of the Commission's advisory bodies[77] in producing evidence that is (in specific cases, as per *Sandoz*) binding for Member States.[78]

3. *Lack of Commission enforcement*

On the other hand, the lack of any legal action undertaken by the Commission under Article 11 makes its legal effects ambiguous, considering the different additional restrictions adopted by various Member States following the initial spread of the omicron variant in late 2021-early 2022.[79] However, the Commission took no legal action against these Member States.

The two cases[80] which attacked the regulation based on Article 11 have been *Abenante*,[81] lodged on 30 August 2021, and *OG and others*,[82] lodged on 9 December 2022. However, both of those were brought by individuals, not by the Commission against a Member State imposed restriction. In *Abenante*, the applicants complained about their fundamental right of free movement being subject to undergoing "invasive medical treatments" (testing or vaccination) without consent, and "manifestly at variance with any scientific standard".[83] However, neither from the action nor from the Court's decision is it clear why Article 11 was invoked, as the case did not concern a national measure, but rather the national implementation of the regulation (Italian Green Pass).

In *OG and others*, the complainants did invoke Article 11, but in relation to the limited temporal validity of the vaccination pass *imposed by the Delegated Regulation 2021/2288*, not Member State action. However, the Court declared the application manifestly unfounded due to the lack of direct legal effects on the applicants.[84]

The lack of case-law represents a major problem when determining what effect Article 11 of the DCCR regulations had on the status quo at the time. The extremely limited case-law failed to indicate whether the explicit call for scientific evidence had a practical effect

[76] And without further institutional reforms, unlikely to be so – see Renda and Castro (n 60); Jordana and Triviño-Salazar (n 59).

[77] *Criminal proceedings against Léon Motte* (1985) ECJ Case 247/84; *Criminal proceedings against Sandoz BV* (n 24). See discussion above in III.A.1.

[78] It is also perhaps indicative of EU agencies' widening mandates – see e.g. (albeit in a different field: aviation rather than public health) M Simoncini, "The Erosion of the Meroni Doctrine: The Case of the European Aviation Safety Agency" (2015) 21 European Public Law 309.

[79] Conditions such as filling in forms or pre-registering, additional testing, or recent vaccination – see the portal Re-Open for historical data per Member State <https://reopen.europa.eu>.

[80] As of writing this Article, though as we explain *infra* further case-law on this basis is unlikely.

[81] *Abenante and Others v Parliament and Council* (2022) Court of Justice of the European Union (General Court) T-527/21.

[82] *OG and Others v European Commission* (2024) ECJ C-754/22 P.

[83] *Abenante and Others v Parliament and Council* (n 76) para 22, machine translated from the original in Italian.

[84] *OG and Others v European Commission* (n 81) para 36.

on the requirements in EU law. This is unfortunate and, given that neither of these regulations are still in force, it is something that will not change in the future. This makes it impossible to go beyond an academic discussion on these issues. Given this, it is not possible at this stage to say with certainty what effects similar provisions could have in a future pandemic situation.

V. Conclusions and further research

The aim of this paper has been to discern whether Article 11 of the DCCR has had an impact on evidentiary requirements in EU free movement law. In section II, we analysed the provision of Article 11 of the DCCR, specifying what kind of scientific evidence the regulation called for, the role it played in proportionality analysis, and the precautionary principle. In section III, we analysed the role scientific evidence played in justifying movement restrictions (in the form of evidentiary standards) that existed in the case-law prior to the adoption of the DCCR. This framework allowed us to evaluate the impact of Article 11 of the DCCR, in section IV.

Compared to the existing body of law, Article 11 of the DCCR functioned as an attempt at harmonisation by codifying some of the existing evidentiary requirements found in the case-law. It required Member States to abide by certain requirements, such as adopting measures based on valid scientific evidence, and adhering to the principles of proportionality and precaution, though it failed to mention other standards, such as carrying out a risk assessment.[85] It also imposed one new requirement – Member States had to consider the scientific work of the ECDC in tracking the spread of Covid-19. In this way, the DCCR gave legal power to the previously non-binding recommendations issued by the ECDC, giving it indirect power to (arguably) shape movement restrictions of certificate holders. On the other hand, the impact of the Article has been limited due to the lack of any Commission enforcement against additional restrictions imposed by Member States during the period of the regulation's application. The lack of action casts doubt on the practical validity of such provisions. Unfortunately, given that neither regulation is in force any longer, we are unlikely to ever get a definitive answer to this question. The authors of this paper would argue that further research focusing on the reasons for the lack Commission legal action from the Commission (e.g. to determine if the reason lay in the Member States' assiduous compliance with Article 11's restrictions, or if there were other, not necessarily legal, reasons) would be useful.

To conclude, the meaning of Article 11 can be summarised as an attempt at harmonising a narrow area, i.e., free movement of certificate holders, for a limited amount of time, though wider harmonisation may not have been possible considering the limited competences of the Union in public health matters. It also shed some additional light on what type of scientific evidence can be used to justify restrictions. However, as scientific research is constantly evolving, it is possible that a more specific provision would have been inherently impossible, though in future health crises, more clarity for legislators and policymakers in terms of what is considered acceptable scientific evidence would be welcome.

[85] Such requirements nevertheless remain binding as part of the case-law.

Cite this article: D Fabcic Povse and P Quinn (2025). "Standards for Including Scientific Evidence in Restrictions on Freedom of Movement: The Case of EU Covid Certificates Scheme". *European Journal of Risk Regulation* **16**, 228–241. https://doi.org/10.1017/err.2024.51