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The Corona Crisis (Covid-19 Pandemic) and the European Union (EU) – Health Policy as a Topic for the Conference on the Future of Europe –

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The article deals with the possibilities and limits of European action in the fight against pandemics on the basis of legal and economic criteria. The Corona crisis has shined the spotlight on EU's seemingly fumbling response in dealing with the pandemic. If the EU appears to be not effective in this regard, it is because it only has coordination competence in the area of health policy and is dependent on the consensus and cooperation of all Member States in its measures (e.g. rules on vaccine procurement and vaccination passport). It is submitted that only a common European strategy can avoid border controls and introduction of measures effective in dealing with the pandemic. Further, it is shown that there is a discrepancy between the allocated European task versus the competence necessary to achieve it efficiently. This could be resolved by means of an addition to the competence, while taking into account the criteria of the subsidiarity principle. A proposal to enhance the EU competence by adding a subsection to Art. 168 (4) TFEU complete with wording is made.

I. European Promises in the Corona Crisis

Holding up the noble goals enshrined in the European Treaties as beacons, political actors of the European Union (EU) often promise the stars to its citizens. However, sometimes the European institutions fail to "deliver" on these promises due to insufficient competences. For example, "the EU" envisages a stable euro area (Art. 119 (2) TFEU), but as the shocks from the 2008 global financial crisis and the resultant sovereign debt crisis have shown, fulfilment of this promise cannot be guaranteed due to a lack of economic and fiscal policy competences (cf. Art. 121 TFEU). Similarly, "the EU" promises to its citizens freedom of movement without border controls in an "area of freedom, security and justice" (Art. 67 TFEU), but as the temporary reappearing of border controls during the migration crisis and the security alarm following the terrorist attacks in Paris, Brussels and Berlin made clear that there are no guarantees to this effect.[1] Lastly, and what also brings us to the theme of this paper – "The EU"

[1] For details on this and on the euro area, see *Calliess*, Öffentliche Güter im Recht der EU, 2021, pp. 19 ff. and 45 ff. (available online: DOI 10.11586/2020072).

promises its citizens a European health policy (Art. 168 TFEU & Art. 35 Charter of Fundamental Rights of the EU), but as we are in the throes of a pandemic, the effects of which are felt Europe wide as they are globally, the EU's role appears limited to mere coordination of Member States. In such circumstances, these ambitious goals resting on insufficient competences make the EU appear incapable of action and undeserving of credibility in the eyes of its citizens time and again.

Currently, this problem is well illustrated by the debate on the European Commission's handling of the joint procurement of vaccines for its 27 Member States. The problem here was that the perception differed from reality. While the Commission appeared to be in charge, in reality, it could only *coordinate* the decision making among Member States by consensus – a fact often overlooked by public. A steering committee consisting of representatives of all 27 members as well as a joint negotiating team consisting of representatives of the Commission, Germany, Spain, Poland, Italy, France, Sweden and the Netherlands, apparently handled the negotiations with the vaccine manufacturers. However, according to available information, the decision as to how many doses of vaccine were to be pre-ordered from which manufacturer was only made by the individual Member States for themselves. Based on this, one might conjecture that economically less prosperous Member States, which also shaped the decision of the steering committee, pushed for larger quotas of the cheaper vaccines to be ordered. Therefore, a costly spreading of ordering, as in the case of the US orders, was apparently omitted. As a consequence, not enough vaccines were ordered. While many things seem to have gone wrong, a genuine European vaccine procurement strategy was never possible to begin with, primarily because there is no adequate competence for that.[2] Therefore a real cross-border European strategy in the fight against the pandemic could not be developed. Left to their own devices, Member States have reimposed controls at the internal borders where they deemed it necessary. This not only impedes free movement of persons in the internal market but also the free movement of EU citizens in the "area of freedom, security and justice", the so-called Schengen area. While internal borders have reappeared, there is still no policy addressing entry of persons into the external EU border. It is due to this incoherent approach that any national protective measures employed end up seeming ineffective in the face of a pandemic which defies borders.[3]

[2] Cf. "Das Impfstoffdrama", Der Spiegel No. 52, 19.12.2020, 30; "Corona: Did the EU save on vaccines in the wrong place?", Ärzteblatt, 21.1.2021 (available online).
[3] In particular on the coherence requirement in the EU, cf. *Ruffert,* in: Calliess/Ruffert (eds.), EUV/AEUV, 5th ed. 2016, Art. 7 TFEU, para. 2 et seq. as well as *Calliess,* ibid., Art. 13 TEU, para. 2.

II. General test criteria for a transfer of competence to the EU

1. Objectives and tasks of the EU

States are tasked with attaining goals pertaining to the realization of common good[4], or public goods, as referred to in economics. [5] Art. 3 TEU transfers (up-zones) some of these goals and tasks to the EU with a view that these are carried out adequately and that public goods, especially those having a cross border dimension are safeguarded. Had the states been left to their own devices, they would have been "overloaded" with solving the problems peculiar to the cross-border context.[6]

This "overload" can generally be concretized on the basis of the principle of subsidiarity. In this respect, two sets of questions must be distinguished: On the one hand, there is the question of whether and how a competence transferred to the EU should be *exercised to* achieve a goal. This means, whether the EU can and should *act at all*, and if so to what extent. To answer this question regard must be had of the principle of subsidiarity and proportionality (Art. 5 TEU).[7] Art. 5 (3) TEU formulates firstly, a negative criterion according to which, the EU may act in cases where action by the Member States alone may not be "sufficient" to solve a problem. In addition to this, secondly, according to a positive criterion, the EU must be able to act "better" than the Member States, a fact to be evidenced by evaluative comparison.[8] On the other hand, the question as to whether a competence to attain an objective should be transferred to the EU in the first place is a political decision and legally carried out by way of treaty amendment through procedures specified under Art. 48 TEU. Within this framework of competences conferred by such treaty amendment, the criteria of the principle of subsidiarity can, of course, only be applied by analogy.

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[4] *Calliess*, Gemeinwohl in der Europäischen Union – Über den Staaten- und Verfassungsverbund zum Gemeinwohlverbund, in: Brugger/ Kirste/ Anderheiden (eds.), Gemeinwohl in Deutschland, Europa und der Welt, 2002, p. 173ff.

[5] For an overview, see *Steinbach/van Aaken*, Ökonomische Analyse des Völker- und Europarechts, 2019, p. 49 ff. with a general application of economic methods of analysis to European law reference areas on p. 147 ff.

[6] *Dietz/Ostrom/Stern*, The Struggle to Govern the Commons, Science 302 (2003), p. 1907 ff. and *Kaul/Blondin/Nahtigal*, Introduction: Understanding Global Public Goods, in: Kaul (ed.), Global Public Goods, 2016, p. XIII ff.; in addition, in overview *Steinbach/van Aaken*, Ökonomische Analyse des Völker- und Europarechts, 2019, p. 49 ff.

[7] See European Commission, Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. The principles of subsidiarity and proportionality – strengthening their role in EU policy-making, COM (2018) 703 final, 23.10.2018.

[8] *Calliess*, Subsidiaritäts- und Solidaritätsprinzip in der EU, 2nd ed. 1999, p. 65 ff. including a test grid on p. 271 ff. with further references; most recently *ibid,* Öffentliche Güter im Recht der EU, 2021, p. 22 ff. (available online).

Considering the above and the criteria applicable in the context of economic theory for the provision of (European) public goods[9], certain avenues of EU action emerge (while keeping the principle of subsidiarity under Art. 5 para. 3 TEU in mind). These are areas wherein Member States alone cannot act "sufficiently" well enough to provide for and realise a European public good because of "policy spillovers". Therefore, with superior means at its disposal, the EU is better equipped to act in these areas ("economies of scale").[10] When employed correctly, in these areas EU measures add value[11] and thus (in the language of politics[12]) strengthen European sovereignty or autonomy. Put simply, this advantage is achieved by strength in numbers (of Member States) as well as through joint European action (the so-called "Brussels effect").[13]

2. Contents of delegated objectives and tasks exceeding competences

Before delving deeper into this discussion, it ought to be made clear that the tasks and objectives of the EU should not be conflated with its competences (cf. e.g. for environmental policy in Art. 192 TFEU). For the objectives and tasks of the EU (Art. 3 TEU, more specifically e.g. environmental policy under Art. 191 TFEU) do not necessarily always correspond to a competence in the Treaties. This is the case, for example, in the area of European social policy (cf. Art. 3 para. 3 TEU and Art. 151 on the one hand and Art. 153 TFEU on the other), health policy (cf. Art. 3 para. 3 TEU and Art. 168 para. 1 and 5 TEU) or economic and monetary union (cf. Art. 119 on the one hand and 121 TFEU on the other).

In other words, certain objectives and tasks of the EU aim higher by specifying contents beyond the competences currently conferred upon the EU in the Treaties. This leads to a discrepancy within the European order of competences and the EU being unable to deliver these ambitious goals. A current example of this is the goal of attainment of a high level of human health in Union policies specifically the fight against pandemics and in particular the ambitious proposal of the European Commission to build a "European Health Union" that is intended to reinforce

[9] Vgl. *Fuest/Pisani-Ferry,* A Primer on Developing European Public Goods, EconPol Policy Report 16, 2019, S. 7 ff.
[10] *Calliess*, Öffentliche Güter im Recht der EU, 2021, p. 22 ff. (available online).
[11] Vgl. *Fuest/Pisani-Ferry,* A Primer on Developing European Public Goods, EconPol Policy Report 16, 2019, S. 7 ff.
[12] Cf. Press and Information Office of the Federal Government, Meseberg Declaration. Renewing Europe's Promise for Security and Prosperity, 19 June 2018, Press Release 214.
[13] On this, from a legal perspective, *Calliess*, Finanzkrisen als Herausforderung der internationalen, europäischen und nationalen Rechtsetzung, VVDStRL 71 (2012), p. 113 (esp. 175 f.); in depth *Bradford,* The Brussels effect, Northwestern University School of Law, Vol. 107, No. 1 (2012); on this in context: *Hartmann/Lucas Areizaga*, in: Kirchhof/Keller/Schmidt (eds.), Europa in Vielfalt geeint!, Munich 2020, p. 101 ff.

the EU's resilience for cross-border health threats by more comprehensive strategies and – among others – more binding measures.[14]

III. The Corona pandemic and the limits of EU competence in the field of health policy

The challenges described above are exacerbated by the Corona crisis, which has alerted us of the fact that the competences conferred upon the EU in the area of public health, in contrast to environmental and consumer protection policy are insufficient. While the ECJ recognises a "general principle" which demands that health "must undoubtedly be given priority"[15], particularly in relation to economic considerations, the Member States remain "masters of health policy".[16]According to Art. 168 (1) TFEU, the EU's competence is generally limited to activities that complement, promote or coordinate the health policies of the Member States.[17] This limited competence of the EU remains unaltered by Art. 35 of the Charter of Fundamental Rights of the EU, which postulates a "right of access to preventive health care and medical treatment". Although arguments for a protective dimension of European fundamental rights ("duty to protect") have been advanced in case law and literature[18], Art. 51 (1) sentence 2 and (2) of the Charter make it clear that the rights listed therein may not lead to an expansion of the EU's competences.[19]

According to Art. 168 (2) TFEU, the Commission may, "*in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation*".

In exercise of such coordination by the EU, the competence of the Member States remains unaltered i.e. it is not – as in the case of binding legislation – *europeanised* or even limited (cf.

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[14] Communication from the Commission COM(2020) 724-727 final, 11.11.2020.
[15] ECJ, Case C-221/10 P, ECLI:EU:2012:216, para. 99 – Artegodan GmbH.
[16] *Berg/Augsberg*, in: Schwarze/Becker/Hatje/Schoo EU-Kommentar Art. 168 TFEU Rn. 16; *Mögele*, EuZW 2020, 297.
[17] *Kingreen*, in: Calliess/Ruffert (eds.), EUV/AEUV, 5th ed. 2016, Art. 168 TFEU, para. 3 et seq. and 13 et seq.; in-depth *Thym/Bornemann*, in: Huster/Kingreen (eds.), Handbuch Infektionsschutzrecht, 2021, ch. 2 para. 49 et seq.; differentiating *Wallrabenstein*, in: Hatje/Müller-Graff/Wegener (eds.), Enzyklopädie Europarecht, Europäische Querschnittpolitiken, vol. 8, Baden-Baden 2014, § 8, para. 65 ff; from practice: *Maass/Schmidt*, Die Entwicklung des EU-Gesundheitsrechts seit 2012, EuZW 2015, 85 ff.
[18] *Calliess*, Dimensions of Fundamental Rights – Duty to Respect versus Duty to Protect, in: Pünder/Waldhoff (eds.), Debates in German Public Law, Oxford/Portland 2014, p. 27 et sq.
[19] *Kingreen*, in: Calliess/Ruffert (eds.), EUV/AEUV, 5th ed. 2016, Art.51 GRCh, marginal no. 6 speaks in this respect of a "matter of course".

Art. 2 para. 2 TFEU). In this sense, within the paradigms of the public health competence, the EU can merely facilitate coordination among Member States who make decisions themselves by unanimity. This shows that the real power remains in national hands (Art. 2 para. 3 and 5 TFEU).[20] How this unfolds in practice is shown for instance when the EU recently attempted to address the Corona-crisis by "inviting"[21] manufacturers of masks and respirators to "immediately increase production". As such, pursuant to Art. 168 (2) TFEU, the Commission cannot bind/commit the Member States to any such joint procurement without their consent, so that nothing more (but also nothing less) than a voluntary agreement on the joint procurement of medical equipment via public tenders would be required. Accordingly, as it appeared on the outside, the Commission would carry out the procurement procedures, but its acts were contingent on Member States' consent who formally remained the purchasers of the products.[22] In this way – similar to[23] the procurement of vaccines[24] – while outwardly the EU appears to act, the real mandate remains with the Member States who are deciding by unanimity. Consequently, responsibility and competence diverge here. This means that right from the beginning, there was a danger that the EU could be held responsible for anything that goes wrong during the procurement process, even though it never could or did act on its own accord.

This legal situation is reflected in the exclusion of any harmonisation of the laws and regulations of the Member States (Art. 168 (5) TFEU). This prohibition also covers measures

"*... designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health ...*",

On the basis of its limited competence, the EU has been able to establish a network of procedures and institutions that serve to protect human health in the event of a risk of infection.[25] For example, Decision 1082/2013/EU on improving cooperation and coordination enables epidemiological surveillance and monitoring, early detection and control of diseases

[20] *Calliess*, in: Calliess/Ruffert (eds.), EUV/AEUV, 5th ed. 2016, Art. 6 TFEU, para. 5 and 12 et seq. and on Art. 2 TFEU, para. 19 et seq.
[21] Communication from the Commission COM(2020) 112 final, 13.3.2020, 4.
[22] *Thym/Bornemann*, in: Huster/Kingreen (eds.), Handbuch Infektionsschutzrecht, 2021, ch. 2 marginal no. 16. with further references.
[23] Different *Thym/Bornemann*, in: Huster/Kingreen (eds.), Handbuch Infektionsschutzrecht, 2021, ch. 2 marginal no. 18, who in this respect apparently assume that this is a supranational procurement measure.
[24] Cf. Commission Communication COM(2020) 245 final, 7.6.2020.
[25] Cf. the overview in *Thym/Bornemann*, in: Huster/Kingreen (eds.), Handbuch Infektionsschutzrecht, 2021, ch. 2 marginal nos. 44 ff. and 68 ff.

was made in close coordination between the Union and the Member States. A number of bodies work together in close cooperation within this network. For instance, central to this coordination is the establishment and maintenance of an early warning and response system as well as the work of a "Health Security Committee" composed of representatives of national health authorities working in close coordination with the Commission.[26] Moreover, working alongside the European Medicines Agency (EMA)[27], there is also the Stockholm-based European Centre for Disease Prevention and Control (ECDC). The ECDC is an independent agency which collects information, identifies and assesses hazards, based on which it can issue expert opinions. In 2013, the ECDC was entrusted by the aforementioned Decision 1082/2013/EU with the task of operating and coordinating a transnational network consisting of itself, the Commission and the Member States for the epidemiological surveillance of communicable diseases.[28] In addition, the ECDC operates an early warning and response system.

Because of the prohibition on harmonisation arising from Art. 168 (5) TFEU, the "European vaccination passport" currently under discussion should actually also be part of this network. In its proposal for a regulation pertaining to this vaccination passport dated 27.3.2021, however, the Commission is relying on Art. 21 (2) TFEU pertaining to the right of every EU citizen to move and reside freely within the territory of the Member States, as legal basis which, as will be shown below – raises questions.[29]

It is clear from these current examples that both the network of bodies outlined in the area of European health protection and the proposal for a European vaccination passport must be done through non-binding measures[30] typical of a coordination competence. The focus must thus be on achieving voluntariness and consensus between the Member States given the prohibition on harmonisation arising from Art. 168 (5) TFEU. Furthermore, this measure does not qualify to be an exception to such prohibition under Art. 168 (5) TFEU which would have allowed the

[26] Cf. 1 and 8 et seq. of Decision (EU) No 1082/2013; regarding the proposed strengthening of this network by binding measures on the Member States see Communication from the Commission COM(2020) 727 final, 11.11.2020.
[27] Regulation (EC) No 726/2004; on this *Orator*, Möglichkeit und Grenzen der Einrichtung von Unionsagenturen, 2017, p. 142 et seq.; regarding the proposed strengthening of EMA see Communication from the Commission COM(2020) 725 final, 11.11.2020.
[28] Cf. Art. 4 et seq. Regulation (EC) No 851/2004; *Orator*, Möglichkeit und Grenzen der Einrichtung von Unionsagenturen, 2017, p. 131 f.; regarding the proposed strengthening of ECDC and its network by – among others – binding measures on the Member States see Communication from the Commission COM(2020) 726 final, 11.11.2020.
[29] Proposal for a Regulation on a framework for the issuance, verification and acceptance of interoperable certificates attesting vaccination, testing and recovery with a view to facilitating free movement during the COVID 19 pandemic (digital green passport): see COM(2021) 130 final.
[30] See in depth *Schoenfleisch*, Integration durch Koordinierung? 2018, p. 7 ff. and 109 ff.

current approach. An exception to the prohibition on harmonisation of national laws only applies in case of narrowly defined areas explicitly listed in Art. 168 (4) TFEU, which concern measures intended to "take account of common security concerns" (Art. 4 (2)(k) TFEU) where the EU may have full (shared) legislative competence. According to Art. 168 (4) TFEU, this exception only applies to:

"*a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;*

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use."

Currently only these above-listed measures can qualify as "*common safety concerns in public health matters*" as defined by Art. 4 (2)(k) TFEU. Not surprisingly they reflect competences transferred to the EU level in the course of past political experience with crises (HIV blood products, BSE, EHEC).[31] The consequence of this is that the Member States can also only be bound by the European requirements within the scope of application of Art. 168 (4) TFEU. Coming back to the example of the "European Health Union" lit c) was used (beside Art. 114 TFEU) as a legal basis for the strengthening of EMA by a clear framework regarding activities to be deployed in preparation for and during public health emergencies. With the objective of an improved preparedness the regulation aims at enhancing the Union's capacity to react quickly, efficiently, and in a coordinated manner to such emergencies. This preparedness should be achieved among others by the development of common tools and agreed methods for monitoring, reporting and data collection by EMA.[32]

[31] *Sander*, ZEuS 2005, 253 et seq.; *Kingreen*, in: Calliess/Ruffert (eds.), EUV/AEUV, 5th ed. 2016, Art. 168 TFEU, para. 18 et seq.; in-depth *Schmidt am Busch*, Die europäische Gesundheitssicherung im Mehrebenensystem, 2007;
[32] Communication from the Commission COM(2020) 725 final, 11.11.2020.

IV. Health protection in the internal market

The establishment of a common market or internal market[33] has been a core objective of the European Economic Community since it was founded in 1957 and continues to be one of the central tasks of the EU today according to Art. 3 (3) TEU. Art. 26 (2) TFEU defines the internal market as "an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty". In this respect, it is about the merging of national markets into a single market in which goods and persons can circulate without border controls or other restrictions as freely as possible. The realisation of the internal market is based on two – ideally complementary – strategies, namely positive and negative integration. [34]

1. Positive integration

Within the framework of positive integration, the European legislator realizes freedom of movement in the internal market by harmonisation. In this respect, above all, the general norm of Art. 114 TFEU exists, but there are also specific competences pertaining to free movement of persons (e.g. Art. 21 para. 2, Art. 46, 50, 53 TFEU) which allow the EU to harmonise Member State's legislations which may affect the smooth functioning of the internal market.[35] Such Member State legislation could also be those aimed at protection of health from pandemics. In this manner, the limited competence of the EU under Art. 168 TFEU may be supplemented. This means that in the internal market, besides Art. 9 TFEU coupled with 168 (1) TFEU which provide for policy on protecting health, Art. 11 TFEU[36] concerning environmental policy, Art. 12 TFEU on consumer protection policy and Art. 147 (2) TFEU on employment policy, there are also respective national competences. These cross-cutting tasks must therefore always be taken into account in all EU measures in other areas, including in the context of internal market-related legal harmonisation pursuant to Art. 114 (1) TFEU. This is underlined not in the least by Art. 114 (3) TFEU, which directs the Commission to assume a

[33] This was preceded by the Commission's White Paper on "Completing the Single Market" of 14.6.1985, COM(85) 310; on this and on the conceptual delimitation *Korte* in: Calliess/Ruffert (eds.), EUV/AEUV, 5th ed. 2016, Art. 26 TFEU, para. 2 ff. and 20 ff.

[34] See *Scharpf*, Negative and Positive Integration in the Political Economy of European Welfare States, in: Marks/Scharpf/Schmitter/Storck (eds.), Governance in the European Union, London 1996, p. 15 ff.; *Korte*, in: Calliess/Ruffert (eds.), EUV/EGV, 5th ed. 2016, Art. 26 TFEU, para. 10 ff. and 30 ff.

[35] For more details, see the study by *Ludwigs*, Rechtsangleichung nach Art. 94, 95 EG-Vertrag, 2004.

[36] *Calliess*, Die neue Querschnittsklausel des Art. 6 ex 3c EGV als Instrument zur Umsetzung des Grundsatzes der nachhaltigen Entwicklung, DVBl. 1998, 559 ff.

high level of protection in its proposals for legislative harmonisation with regard to some of these policy areas, e.g. health protection.

Art. 114 (1) TFEU in its wording appears to provide a carte blanch to the EU to enact "measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market". It is precisely this wording which leads to recurrent questions as to how this seemingly no holds barred cross-sectional competence is to be seen alongside other specific substantive competences conferred upon the EU by the Member States to ensure that alongside the smooth functioning of the internal market, public welfare can be protected. This is to be done through policies in the areas of for example environmental, consumer and health protection. Also debated is the question of where does the "limitation" on EU competence of health protection under Art. 168 TFEU stop and where does the general harmonization power under Art. 114 TFEU begin?

a) Leading decision on the tobacco advertising ban

Pertinent to this question, the case law of the ECJ on the European tobacco advertising ban comes to mind,[37] which continues to be the subject of numerous conflicts, debates and disagreements to this day.[38] In its first tobacco advertising ban ruling, the ECJ emphasised in clear, albeit terse terms that other ancillary articles of the TEU may not be used as a legal basis to circumvent the express exclusion of any harmonisation provided under Art. 168 (5) TFEU. At the same time, however, it pointed out that this is not to say that harmonisation measures adopted on the basis of Art. 114 (1) TFEU may not incidentally impact protection of human health. As such, under certain circumstances, health protection may even play a "decisive role" in the context of the intended measure. The ECJ arrived at this conclusion based on a joint reading of Art. 114 (3) TEU and the corresponding cross-cutting health policy clause of Art. 168 (1) TFEU, which obliges the Union institutions to also strive to achieve a high level of health protection in the pursuit of other Treaty objectives. The latter however, was only deemed to be a "secondary objective" or an incidental to the main regulation.[39]Against this

[37] ECJ, Case C-376/98 Germany v. Council and Parliament [2000] ECR I-2247; on this, the contributions in: *König/Uwer* (eds.), Grenzen europäischer Normgebung, 2015, p. 13 ff.
[38] ECJ, Case C-358/14, ECLI:EU:C:2016:323, para. 26, 32 et seq. (Poland v. Parliament and Council); critical of recent case law *Nettesheim*, EuZW 2016, 578 (580).
[39] *Berg*, Gesundheitsschutz als Aufgabe der EU, 1997, p. 463 ff.

background, the ECJ then examines firstly, whether the measure in question supposedly based on the internal market competence under Art. 114 TFEU:

1. actually serves to eliminate obstacles to the free movement of goods and the freedom to provide services [40]; and secondly, whether it
2. actually contributes to the elimination of distortions of competition.[41] Within the framework of this objective of Art. 114 (TFEU), the ECJ specifically examines whether the distortions of competition which the act seeks to eliminate are appreciable. If this condition were not met, there would be practically no limits to the competence of the Community legislator. [42]

The ECJ considers this requirement of actually serving to eliminate trade barriers and noticeable distortions of competition in the internal market to be mandatory, and therein makes clear that Art. 114 (1) TFEU contains a general, but not unrestricted competence to enact harmonization measures. Any measure apart from one which actually fulfills this requirement – as emphasised by the ECJ – must be regarded as circumvention of Art. 168 (5) TFEU which prohibits harmonisation of areas outside the scope of those listed in Art. 168 (4) TFEU. [43] This leads us to the conclusion that measures intending to combat pandemics such as Corona virus cannot be based on the internal market competence of Art. 114 (1) TFEU just because it allows the possibility of harmonisation to the European legislator.

The clear wording of Art. 168 (5) TFEU and the accompanying conclusions must also apply *mutatis mutandis* with regard to the specific free movement competences of Art. 21 (2) as well as Art. 46, 50, 53 TFEU. This is illustrated by way of, for example, Recommendation (EU) 2020/1475 of 13.10.2020, which, pursuant to Art. 288 (5) TFEU is non-binding and is explicitly "only" intended to ensure a coordinated approach or enhanced coordination if a Member State wishes to take measures to restrict freedom of movement on public health grounds. Concerning the risk of cross-border infection chains, this was in turn supplemented by another Recommendation (EU) 2021/119 dated 1.2.2021.[44]

[40] ECJ, Case C-376/98 Germany v Council and Parliament [2000] ECR I-2247, paras 95-102.
[41] ECJ, Case C-376/98 Germany v Council and Parliament [2000] ECR I-2247, paras 106-114.
[42] ECJ, Case C-376/98, Germany v. Council and Parliament, [2000] ECR I-2247, para. 106 et seq.
[43] *Stein*, Die Querschnittsklausel zwischen Maastricht und Karlsruhe, in: Due/Lutter/Schwarze (eds.), FS Everling, vol. II, 1995, 1439 (1441 ff.).
[44] OJ EU L 337, 14.10.2020, p. 3 and OJ EU L 36 I, 2.2.2021, p. 1 respectively.

b) European vaccination certificate

Contrary to what has been discussed above, the Commission has relied on Art. 21 (2) TFEU as legal basis in its proposal for a European vaccination passport (so-called "digital green passport") submitted on 17 March 2021. This proposal is likely to face the same objection as the one which was subject of the ECJ decision on tobacco advertising ban. On the flip side, it can be argued that this measure serves the freedom of movement, as its focus is on safe travel during a pandemic, such that health protection is only incidentally affected. Indeed, the regulation proposes that outcomes of having COVID-19 vaccination, survived COVID-19 illness or tested negative are to be recorded in the forgery-proof certificate based uniform criteria. In concrete terms, this certificate can be converted into a QR code that can be presented on paper or smartphone just like a train ticket.

The exercise of EU's competence here could also have been made possible by its coordination competence under Art. 168 TFEU. Indeed, the development of a technical platform through which the vaccination card databases of the Member States can exchange information with each other and thus verify and mutually recognise the "certificates" can be achieved in this manner. In this respect, the expectation is that Member States will set up national databases and oblige testing and vaccination centers as well as doctors to upload all relevant data on vaccinations given, negative test results and illnesses survived. Above all, member states should remain free to decide for themselves which concrete benefits they might wish to link to the green certificate. On the other hand, if they continue to require travelers holding these certificates to quarantine or get additionally tested, they will have to notify the Commission as well as all other Member States and justify why such additional requirements are needed.[45]

The fact that despite having proposed a regulation on the legal basis of Art. 21 TFEU, the Commission has willingly limited itself to the role of a coordinator/mediator which would be rather in accordance with the coordination competence of Art. 168 TFEU. Having acted in this way, the Commission has skillfully avoided a potential outcome similar to the one in the ECJ decision on the ban on tobacco advertising.

[45] See in detail the proposal for a Regulation on a framework for the issuance, verification and acceptance of interoperable certificates for vaccination, testing and recovery with the objective of facilitating free movement during the COVID 19 pandemic (digital green passport): see COM(2021) 130 final.

c) Interim result

Resultantly, the EU's role in the area of health and infection control can at best be described as that of having indirect regulatory access over the health and infection control law of the Member States via its competences pertaining to the internal market and freedom of movement. For example, by laying down secondary legislation on authorisation and distribution of medicinal products or vaccines, the EU primarily regulates the free movement of goods in the internal market, while ensuring uniform (minimum) standards of European public good for protecting the health of EU citizens. In this respect, the European Medicines Agency (EMA)[46] is a supranational regulatory agency that enables the EU-wide testing and authorisation of medicines and vaccines via common standards.

2. Negative integration

Where positive integration by way of European harmonisation cannot take place, the EU may resort to negative integration, which is defined by the fundamental freedoms that characterize the internal market. Here, the role of health protection will be limited to that of a justification behind national measures such as export restrictions or border controls.[47]

In its *Cassis de Dijon* ruling[48] on the fundamental freedom of free movement of goods, the ECJ established the principle of mutual recognition, according to which any product lawfully manufactured and marketed in one Member State may also be imported into other Member States where it must be, as a rule, be freely marketable. In this way, it has practically formulated a sort of presumption as to country-of-origin principle for goods in the internal market, according to which, legal and technical regulations of one Member State are in principle to be considered equivalent to another. However, the country of destination can rebut this presumption by defending its national legislation on the basis of written and/or unwritten reasons (e.g. according to Art. 36 TFEU as well as beyond this by way of so-called imperative requirements of the common good). If the justification is found valid, i.e. the country of destination justification outweighs the country of origin principle, the said presumption is deemed to be rebutted with the consequence that there is no mutual recognition, i.e. the internal

[46] Regulation (EC) No 726/2004; on this *Orator*, Möglichkeit und Grenzen der Einrichtung von Unionsagenturen, 2017, p. 142 et seq.
[47] In-depth *Thym/Bornemann*, in: Huster/Kingreen (eds.), Handbuch Infektionsschutzrecht, 2021, ch. 2 marginal nos. 13 ff. and 22 ff. with further references.
[48] ECJ, Case 120/78, [1979] ECR 649, para. 14.

market remains fragmented.[49] In this matrix of internal market regulation, national health protection is one such possible justification in public interest which can be rightly raised and must always be balanced against the European fundamental freedoms namely free movement of goods, services and persons bearing in mind the principle of proportionality.[50] This means that national border controls may be rightfully justified as a measure to curtail the spread of a pandemic. Similarly, export bans imposed by Member States with a view towards securing its own needs of medical products may also be legitimate even though they interfere with the principle of the free movement of goods (Art. 35 TFEU). In this respect, the ECJ has confirmed that "*the need to ensure the regular supply of the country for essential medical purposes* may justify *an obstacle to intra-Community trade*", provided that the specific measure is proportionate.[51] Within the framework of this balance, the national public good of health protection seen from the lens of the European internal market, mediated via the justification test, acquires the character of a European public good in certain aspects. At the same time however, the internal market remains fragmented as a uniform area without border controls. In the wake of the Corona pandemic, the European Commission has emphasized that "essential goods needed to contain health risks can reach all those in need".[52] It could be that this approach to ensure availability of protective equipment across member states through a coordinated strategy as opposed to through harmonization was done with a view to avoid political incursions.[53] However, making the functioning of internal market contingent upon solidarity/ unanimity is neither legally necessary nor compelling.[54]

V. Discrepancies between European objectives, tasks and competences in the field of public health protection

As explained above (under section II.), a treaty amendment will be necessary if a discrepancy between treaty objectives and tasks and the competences conferred upon the EU is to be resolved. This is the case, if there is a gap between European public goods "promised" in the objectives of the Treaties (and by this recognised by all Member States when signing them) and

[49] In detail Calliess, DVBl. 2007, 336 et seq.
[50] For further details, see *Kingreen,* in: Calliess/Ruffert (eds.), EUV/AEUV, 5th ed. 2016, Art. 34-36 TFEU, paras. 74 et seq. and 199 et seq.
[51] ECJ, Case C-324/93, Judgment of 28.3.1995, ECLI:EU:C:1995:84, para. 37 – Evans Medical.
[52] Communication from the Commission COM(2020) 112 final, 13.3.2020, 3.
[53] Cf. European Commission/European Council, Common European Roadmap for the Repeal of COVID-19 containment measures, 11.
[54] *Thym/Bornemann*, in: Huster/Kingreen (eds.), Handbuch Infektionsschutzrecht, 2021, ch. 2 marginal no. 14 with further references.

the competences to which the EU is entitled in this respect, in the course of which the EU either cannot act at all or cannot act sufficiently.

1. Possible gap filling in the area of pandemic protection

Based on the foregoing, it is clear that according to the current allocation in the Treaties, the EU is not sufficiently equipped to take on the fight against pandemics primarily because the European legislative competences in the area of public health policy is limited pursuant to Art. 168 (4) TFEU. In this respect, there is an evident discrepancy between the goals and tasks of the EU on the one hand and the actual competences of the EU on the other. While according to Art. 168 (5) TFEU, the EU should, on the one hand, be able to take action "*combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health*", on the other hand, it may only do so by way of coordinating support measures and not by way of enacting harmonization legislation. As shown above, such coordination competence is not sufficient to ensure effective cross-border pandemic control and avoid the collateral damage caused by border controls mentioned above.

If one also looks (by way of a systematic interpretation) at the catalogue of EU competences, it becomes clear that European strategies and measures to combat pandemics such as the Coronavirus can certainly be classified as "*common safety concerns in public health matters*" under Art. 4 (2)(k) TFEU.

It should therefore be noted that with regard to realizing the European public good of health protection, there is an evident discrepancy between what has been promised in the Treaties versus the actual possibilities of achieving those promises outlined therein. More specifically, the possibilities for action by the EU legislator are insufficient due to the limits on the form of competences. Based on the foregoing, in order to realise European public goods, Art. 168 (4) TFEU on its own would be insufficient and therefore would have to be supplemented by an additional European legislative competence towards combating cross-border pandemics.

Based on the above definition of European public goods (II.) and alongside the application of the standards of the principle of subsidiarity outlined above (here – in the context of an amendment of the Treaty – "only" as a political guideline) both speak in favour of a specific European competence in fighting pandemics. Since a pandemic does not know borders and

spreads across Europe as it does globally, the fact that a common European response will have added value with regard to prevention and control thereof is decisive. At the same time, this would ensure that reimposition of national border controls which restrict the functioning of the internal market and the Schengen area would no longer be necessary and could only be justified in extreme exceptional cases, e.g. in the face of complete inaction on behalf of the EU or an obviously ineffective European strategy. However, in order not to prevent the Member States from doing "more", in the sense of achieving the right balance between the principles of solidarity and subsidiarity[55] and attaining cooperation based on division of labour, the possibility of strengthening protection by way of national action would have to be granted in the Treaty. This would allow decentralised action above and beyond what can be achieved through European harmonisation.

Against this background, a proposal for addition to the legislative competence by a new letter d) to the above-mentioned Art. 168 (4) TFEU could read as follows:

"*Measures for the early notification, monitoring and control of serious cross-border health threats, in particular in the event of pandemics. These measures shall not prevent Member States from maintaining or adopting reinforced protective measures where these are necessary.*"

Such addition to competences would be necessary not least for an (obvious) legal, financial and personnel strengthening of the European Medicines Agency and the European Centre for Disease Prevention and Control, but because, according to the principle of conferral (Art. 5 para. 2 TEU), only clearly defined executive powers as specified within the order of competences under the Treaties can be performed by European agencies.[56] Their work could be supported in the area of research by the establishment of a new agency that would work along the lines of the US Agency for Advanced Biomedical Research and Development (BARDA).

[55] *Calliess*, Subsidiaritäts- und Solidaritätsprinzip in der EU, 2nd ed. 1999, p. 185 ff. with further references.
[56] ECJ, Case C-270/12 – United Kingdom v. European Parliament and Council, ECLI:EU:C:2014:18; in detail *Orator*, Possibilities and limits of the establishment of Union agencies, 2017, pp. 185 et seq. and 459 et seq.

2. Ways of closing gaps in the area of pandemic protection

Under certain conditions, the simplified treaty amendment procedure (Art. 48 (6) TEU) can be used to supplement competences. This is how a new paragraph 3 was added to Art. 136 TFEU to legitimise the European Stability Mechanism (ESM) in the context of the rules of Economic and Monetary Union.[57] However, since the proposed amendment would extend the EU's competences, ordinary treaty amendment procedure pursuant to Art. 48 (2) and (3) TEU without setting up a convention may have to be resorted to.

Every treaty amendment requires the consent of all Member States (cf. Art. 48 para. 4 and para. 6 TEU), so that in the absence of consensus, a "coalition of the willing" may nonetheless proceed.[58] If neither of these mechanisms are successful, a specific treaty under international law between the willing Member States – as was done for example with the European Fiscal Treaty of 2012[59] – may be considered as last resort.

VI. Conclusion

As is clear, there are weighty factual and legal arguments for creating a genuine but specific legislative competence of the EU in addition to what exists under Art. 168 (4) TFEU to enable it to fight against pandemics so that it is no longer hindered by the prohibition of harmonisation in Art. 168 (5) TFEU. As a consequence, the described discrepancy between European goals and competences could be resolved by enabling a common European strategy through which the reimposition of national border controls may be avoided while ensuring effective measures for attainment of the European public good of health during a pandemic. At the same time, such strategy should be deployed – in accordance with the principles of subsidiarity and proportionality – in an open manner that leaves the necessary flexibility and leeway to the Member States should they wish to go beyond the common European measures.

[57] On this, *Calliess*, ZEuS 2011, 213 (275 et seq.); *ibid.*, Die neue EU nach dem Vertrag von Lissabon, 2010, p. 90 ff.
[58] *Piris,* The Future of Europe, 2012, p. 106 et seq.
[59] For further details see *Calliess*, From Fiscal Compact to Fiscal Union? New Rules for the Eurozone, in: Cambridge Yearbook of European Legal Studies, Vol. 14, 2012, p. 101 et seq.