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Strengthening the EU's Response Capacity to Health Emergencies: Insights from EU Crisis Management Mechanisms

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What could a European Union (EU) response mechanism to health emergencies look like in the context of a more integrated Health Union? Despite an increased EU role in the preparedness, monitoring and coordination of health emergencies over the past two decades, Member States' responses to the first wave of COVID-19 were surprisingly uncoordinated. In light of calls to improve cooperation regarding future health emergencies, this article discusses the creation of EU surveillance, preparedness and response mechanisms for health emergencies. Using insights from previous research and secondary literature, we highlight gaps in the existing serious cross-border health threats regulatory framework and discuss opportunities for further EU action. Based on a comparison with other EU crisis management mechanisms (the Banking Union, risk preparedness in the electricity sector and food safety), we discuss different crisis decision-making and coordination models and their potential applicability to the health sector. We then formulate several propositions to strengthen Decision 1082/2013/EU on serious cross-border health threats to streamline ex ante pandemic preparedness and organise emergency responses.

I. Introduction

The current coronavirus crisis exposed the challenges that the European Union (EU) faces in providing joint and timely responses to large-scale pandemics, and more generally to health emergencies. Despite an increased EU role in the preparedness, monitoring and coordination of health emergencies since the 2000s,[1] Member States unilaterally adopted a series of uncoordinated border closures, varying confinement and testing strategies and national measures restricting the free circulation of masks.[2]

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[1] KP Purnhagen et al, "More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak" (2020) 11 European Journal of Risk Regulation 297.

[2] A Alemanno, "The European Response to COVID-19: From Regulatory Emulation to Regulatory Coordination?" (2020) 11 European Journal of Risk Regulation 307.

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These measures limited the EU's effectiveness in combatting the disease and created threats to the well-functioning of the single market and the Schengen zone.

This article contributes to current debates about a Health Union, a topic raised, amongst others, by the European Parliament in July 2020.[3] It looks into possible ways to improve the current EU system for responding to large-scale health crises. We analyse in particular the 2013 EU Decision (1082/2013/EU) on serious cross-border health threats, which is the primary tool to manage health crises in the EU. The organisation of the health crisis management regime has remained overlooked so far, and should be a critical aspect of any future EU response to pandemics. We adopt a comparative perspective, drawing lessons from other EU crisis management mechanisms.

Over the past two decades, the EU has indeed considerably expanded its ability to manage cross-border crises. It has not only developed monitoring and decision-making capacities at the EU level,[4] but it also has adopted multi-level arrangements across policy domains to steer coordination between Member States and streamline crisis preparedness and response.[5] Crisis management in the EU is fundamentally about how to coordinate Member States' actions to prepare for and respond to cross-border threats.[6] Coordination is a challenging issue in crisis management,[7] but it is even more so in the EU, where multiple layers of authorities need to cooperate.[8] Arguably, the issue of how to coordinate crisis response in the EU comes down to two critical dimensions.[9] First, who has the power to make decisions (ie who has the competence and the ability to exert or acquire it: the EU or Member States)? Traditionally, crisis management is a core state power,[10] characteristic of sovereignty. Yet, in a Union that is more and more integrated, crises span across borders and call for joint action at the EU level. The second dimension relates to the question of how the EU can enforce solidarity in crisis management. In other words, how prescriptive can the EU be when intervening in Member States' preparedness and response policies: does the EU incentivise Member States to cooperate, or does it require them to do so through binding arrangements?

These two dimensions – decision-making and prescriptiveness – that characterise EU crisis management regimes in different ways serve as a basis for our discussion. In the rest

[3] European Parliament resolution of 10 July 2020 on the EU's public health strategy post-COVID-19 (2020/2691/RSP). Especially, paragraph AL.1 calls "for the European institutions and the Member States to draw the right lessons from the COVID-19 crisis and engage in far stronger cooperation in the area of health; calls therefore for a number of measures to create a European Health Union".

[4] A Boin, M Ekengren and M Rhinard, *The European Union as Crisis Manager: Patterns and Prospects* (Cambridge, Cambridge University Press 2013).

[5] L Cabane and M Lodge, *The European Government of Crisis* (Oxford, Oxford University Press forthcoming).

[6] J Jordana and JC Triviño-Salazar, "EU Agencies' Involvement in Transboundary Crisis Response: Supporting Efforts or Leading Coordination?" (2020) 98 Public Administration 515; A Boin, M Busuioc and M Groenleer, "Building European Union Capacity to Manage Transboundary Crises: Network or Lead-Agency Model?" (2014) 8 Regulation & Governance 418.

[7] P 't Hart, U Rosenthal and A Kouzmin, "Crisis Decision Making: The Centralization Thesis Revisited" (1993) 25 Administration & Society 12; T Christensen et al, "Comparing Coordination Structures for Crisis Management in Six Countries" (2016) 94 Public Administration 316; Jordana and Triviño-Salazar, supra, note 6.

[8] A Boin, M Rhinard and M Ekengren, "Managing Transboundary Crises: The Emergence of European Union Capacity" (2014) 22 Journal of Contingencies and Crisis Management 131.

[9] Cabane and Lodge, supra, note 5.

[10] P Genschel and M Jachtenfuchs (eds), *Beyond the Regulatory Polity? The European Integration of Core State Powers* (Oxford, Oxford University Press 2013).

of the article, we first analyse the current EU response mechanism to large-scale health threats. We then review different EU crisis management mechanisms that present policy instruments that are potentially relevant for the health regime. Finally, based on these considerations, we argue that, without even changing the current distribution of competences, it is possible to improve the current EU system for responding to cross-border health threats. We propose a series of changes to Decision 1082/2013 to improve the consistency of public health preparedness and coordination of Member States in times of crisis.

II. The current EU health security framework and its limits

Cross-border health crises in the EU illustrate a crisis management regime predominantly based on intergovernmental mechanisms. According to Article 168 of the TFEU, coordination remains a responsibility of Member States, while EU instruments are limited to a supporting role. The EU effectiveness depends to a large extent on Member States' willingness to coordinate.

Article 168 of the TFEU states that the EU complements Member States' national public health policies, in particular when it comes to "monitoring, early warning of and combating serious cross-border threats to health". It thus provides the EU with a significant mandate to act on health risk and crisis management, as long as the principles of subsidiarity and proportionality are respected. The 2013 Decision on serious cross-border health threats (1082/2013/EU) specifies further EU domains of action: risk assessment and epidemiological surveillance, support for national preparedness and crisis management capacities and coordination in response to outbreaks.

1. Risk assessment, epidemiological surveillance and information gathering

Mutualisation of data and surveillance represents the first and most integrated component of the EU action on cross-border health threats. In 1998, mounting consensus amongst Member States on the need to share epidemiological data and identify potential outbreaks led to the creation of a network of national public health agencies (Decision No 2119/98/ECA), together with the creation of an Early Warning and Response System (EWRS). In 2004, Member States supported the creation of an EU-level agency in charge of gathering epidemiological surveillance and risk assessment: the European Centre for Disease Control and Prevention (ECDC).[11] The ECDC has since enlarged its activities to managing the EWRS and to facilitating information sharing among national public health experts.

Over the years, this agency has built a reputation of excellence.[12] However, it remains weak by status and lacks regulatory powers. Its role is restricted to providing assessments and monitoring cross-border health risks in a field already crowded by more powerful

[11] T Deruelle, "Bricolage or Entrepreneurship? Lessons from the Creation of the European Centre for Disease Prevention and Control" (2016) 2 European Policy Analysis 43.

[12] T Deruelle, "A Tribute to the Foot Soldiers: European Health Agencies in the Fight against Antimicrobial Resistance" (2020) Health Economics, Policy and Law 10.1017/S1744133120000213.

national authorities and the World Health Organization (WHO).[13] Furthermore, epidemiological surveillance remains partial and inconsistent,[14] not least because of a lack of involvement from Member States, who regularly fail to fulfil their mandatory reporting obligations.[15] With a budget of €58 million and a staff of 300 people, it is underfunded and understaffed,[16] which makes it all the more dependent on Member States' goodwill.[17]

The SARS-CoV-2 crisis shed light on these limits. The ECDC failed, up until early March, to acknowledge the seriousness of the threat and the lack of preparedness of most Member States. Partial information sent by Member States led the ECDC to declare on 22 January that the risk of the virus spreading to Europe was low and that EU countries were well prepared. A month later, the ECDC told health ministers again that European testing and laboratory capacities were adequate and that the EU containment strategy was a success. It was not until early March that the ECDC raised the alarm on the sanitary situation in Europe.[18] From that moment, the agency, together with the Commission, began issuing guidelines and recommendations on key aspects of crisis management such as social distancing, testing, contact tracing and hospital resilience. However, because these recommendations are not legally binding as provided by the 2013 Decision, Member States, especially at first, did not much coordinate their public health actions and medical countermeasures.

2. Preparedness

The second principal component of EU action on cross-border health threats relates to the coordination of preparedness. Preparedness is on the edge of EU legal competences. While safety and public health are supporting competences for which the EU may coordinate or supplement Member States' actions, matters related to the organisation of national health services remain the exclusive competence of Member States. Yet, crisis preparedness and planning entail, to some degree, action on health systems, which makes it a sensitive topic to address.[19]

This legal ambiguity has translated into the absence of binding provisions. Article 4 of the 2013 Decision loosely provides that Member States "shall consult each other within the Health Security Committee (HSC) with a view of coordinating their efforts to

[13] SL Greer, "The European Centre for Disease Prevention and Control: Hub or Hollow Core?" (2012) 37 Journal of Health Politics, Policy and Law 1001.

[14] SL Greer, "Constituting public health surveillance in twenty-first century Europe" in M Weimer and A de Ruijter (eds), *Regulating Risks in the European Union: The Co-Production of Expert and Executive Power* (London, Bloomsbury 2017) pp 121–41; European Court of Auditors, "Dealing with Serious Cross-Border Threats to Health in the EU: Important Steps Taken but More Needs to Be Done", Special Report No. 28 (Luxembourg, Publications Office of the EU 2016).

[15] PriceWaterhouseCoopers, "European Centre for Disease Prevention and Control, Third independent external evaluation of the ECDC in accordance with its Founding Regulation" (2019).

[16] A Renda and R Castro, "Towards Stronger EU Governance of Health Threats after the COVID-19 Pandemic" (2020) European Journal of Risk Regulation 1.

[17] ECDC, "Statement of revenue and expenditures of the European Center for Disease Prevention and Control for financial year 2018" (2018) C/108/07.

[18] <https://www.politico.eu/article/coronavirus-europe-failed-the-test/>.

[19] M Anderson, M Mckee and E Mossialos, *Covid-19 Exposes Weaknesses in European Response to Outbreaks* (London, British Medical Journal Publishing Group 2020).

develop, strengthen and maintain their capacities". The Decision mostly relies on soft law arrangements, such as the sharing of best practices, guidelines and technical assistance. The most constraining provision mandates Member States to report every three years on their preparedness and response planning, but implementation of this measure was uneven. The first round of reports in 2014 was very partial. The European Court of Auditors (ECA) noted in 2016 the lack of supporting evidence such as national preparedness plans and, more generally, of precise information on individual Member States' capacities and preparedness levels.[20] The ECA further emphasised the weaknesses of a system entirely based on self-assessment, in which the Commission has no mandate to collect or verify information.

3. Coordinating Member States' responses

The third major component of EU action consists in facilitating the coordination of Member States' responses during health crises. In many ways, the SARS-CoV-2 pandemic highlighted that coordination arrangements that rely only on incentives are too weak to allow for a rapid concerted response. Existing instruments proved inadequate, and the setting up of ad hoc structures such as the Commission's Coronavirus Response Team, established on 2 March, added another layer of complexity.

The HSC, created in 2001, is the main EU organisation for facilitating the coordination of Member States. It is an intergovernmental body composed of representatives from Member States. The 2013 Decision strengthened what was initially an informal network and mandated Member States to consult with each other in case of serious cross-border health threats. They do not have an obligation to act jointly, only to inform the HSC and the Commission of all measures that they take, unless the situation is so urgent that the immediate adoption of measures is deemed necessary. In fact, during the first wave of the COVID-19 pandemic, governments frequently overstepped their information and consultation duties on the ground of the urgent character of the threat.

To be fair, the EU itself was quite slow to act, paving the way for such unilateral responses. The current governing structures proved quite difficult to manoeuvre in times of crisis when rapid decision-making and flexible procedures were needed most. The Health Ministers Council took two weeks to meet after Italy requested an emergency session in late January. The meeting on 17 February was more of an aspirational statement on the EU's appropriate level of preparedness than a substantive discussion on how Member States should act to address the looming crisis. The Commission kept urging Member States to coordinate their actions, but these exhortations remained of little consequence. Observers reported that the HSC weekly meetings were too irregular and too short (one hour) to allow for substantive work. Member States attended unevenly: too few at first, then too many to enable detailed discussions.[21]

[20] European Court of Auditors, supra, note 14.

[21] B Stockton, C Schoen and L Margottini, "Crisis at the Commission: inside Europe's response to the coronavirus outbreak" (The Bureau of Investigative Journalism, 15 July 2020) <https://www.thebureauinvestigates.com/stories/2020-07-15/crisis-at-the-commission-inside-europes-response-to-the-coronavirus-outbreak>.

While exceeding the scope of this contribution, it is also important to mention that the 2013 Decision relies to a significant extent on the EU Civil Protection Mechanism (CPM).[22] The CPM aims to facilitate the coordination of responses to disasters (of any kind) through the Emergency Response Coordinating Centre, preparedness training programmes and large-scale exercises. In 2019, Decision 420/2019 strengthened the CPM with the creation of a reserve of additional capacities (RescEU) that notably included medical teams and evacuation capacities. RescEU was mobilised during the COVID-19 crisis when the Commission announced on 19 March the compilation of a strategic stockpile of medical equipment such as ventilators and protective masks. This mechanism has much potential, but the fact that it was quite recent might have prevented it from being more widely used. The EU level proved of limited help to mitigate the shortage of personal protective equipment faced by most EU members in March and April. It was only on 2 May that the Commission announced the delivery of 330,000 facemasks to Italy, Spain and Croatia.

A last aspect of EU preparedness and responses to health crises relates to the joint procurement mechanism, which was first discussed in the aftermath of the 2009 H1N1 pandemic. Article 5 of the 2013 Decision introduced this instrument to facilitate the continuous supply of critical equipment and medicine during crises. It allows Member States to voluntarily pool resources to purchase medical countermeasures such as personal protective equipment or future vaccines. While it may be regrettable that the EU did not use joint procurement before the COVID-19 pandemic hit to establish national stockpiles, it nonetheless activated it in late February 2020 to purchase personal protective equipment and in June 2020 for the purchase of a future vaccine.

Overall, the COVID-19 crisis in the spring of 2020 questioned the adequacy of EU tools to deal with severe cross-border health threats. The crisis emphasised the limits of current arrangements, primarily because of the lack of binding provisions. Coordination in an intergovernmental framework remains, by definition, limited and not up to the new challenges that the EU faces in providing joint and timely responses to large-scale pandemics.

III. Variety of crisis management models in the EU and their applicability to health

The 2013 Decision on serious cross-border health threats is one amongst many crisis management mechanisms that the EU has adopted over the past two decades. As suggested in Section I, these mechanisms vary depending on who makes the decisions (Member States or the EU) and on how prescriptive and binding are EU interventions in harmonising Member States' crisis preparedness and response. Based

[22] C Morsut, "The EU's Community Mechanism for Civil Protection: Analysing Its Development" (2014) 22 Journal of Contingencies and Crisis Management 143; CF Parker, T Persson and S Widmalm, "The Effectiveness of National and EU-Level Civil Protection Systems: Evidence from 17 Member States" (2019) 26 Journal of European Public Policy 1312; M Rhinard, S Hollis and A Boin, "Explaining Civil Protection Cooperation in the EU: The Contribution of Public Goods Theory" (2013) 22 European Security 248.

on these two variables, we selected three cases of crisis management regimes[23] relevant for our discussion: one in which Member States retain decision-making powers, but with an obligation to coordinate through EU institutions (electricity); one in which both the Commission and Member States have competences to manage crises, but with a more precise organisation of coordination (food safety); and one in which the EU has exclusive competence to manage crises and oversee preparedness (banking). We do not intend to be exhaustive in our discussion of these regimes; instead, we focus on characteristics that offer possible options to reform the 2013 Decision on health. For banking and electricity, we rely on interviews carried out by one of the authors in 2018,[24] while for food safety, we rely on secondary sources and academic literature.

1. National decision-making with an obligation to coordinate: electricity

This first case combines intergovernmental decision-making – as in health – with prescriptive and regulatory mechanisms to coordinate crisis policies. The deregulation of electricity markets in the 1990s to establish a single market of energy led to interconnecting electricity transmission networks across Europe.[25] Interconnection brings enhanced security of supply since electricity can flow across regions, but also an increased vulnerability as electricity failures can also cascade across networks. The prevention and resolution of crises is essential, as any power failures can bring down European networks with potentially catastrophic consequences on critical national infrastructures. Electricity is a shared competence: the Commission regulates energy markets, while Member States should maintain security of supply.[26]

The EU recently adopted two prescriptive tools to strengthen the coordination of responses, one technical and one legal, as part of a more general push by the Commission to standardise risk methodologies and define specific requirements for Member States.[27] The first is the Network Code on Emergency and Restoration, developed by the European Network of Transmission Systems Operators for Electricity, reviewed by the Agency for the Coordination of Energy Regulators and enshrined in Regulation 2017/2196/EU. It defined highly specific rules and standards on how to manage power failure within and across borders for operators. This Code focuses on response, while other codes target risk prevention.

The second tool is the Regulation on electricity risk preparedness (2019/941/EU) that established a "common framework of rules" to harmonise electricity preparedness and ensure cooperation between Member States during crises. In contrast to health, this Regulation specifically "requires Member states to cooperate … in a spirit of solidarity", rather than merely inviting them to do so. In terms of surveillance, the

[23] C Hood, H Rothstein and R Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford, Oxford University Press 2001).

[24] TransCrisis project (grant number 649484) under the European Union Horizon 2020 programme.

[25] D Buchan and M Keay, *Europe's Long Energy Journey: Towards an Energy Union?* (Oxford, Oxford University Press 2016).

[26] L Meeus and J-M Glachant, *Electricity Network Regulation in the EU: The Challenges Ahead for Transmission and Distribution* (Cheltenham, Edward Elgar Publishing 2018).

[27] MD Leiren et al, "Energy Security Concerns versus Market Harmony: The Europeanisation of Capacity Mechanisms" (2019) 7 Politics and Governance 92.

Regulation commanded the adoption of common definitions, risk assessment methodology and crisis scenarios. In order to harmonise preparedness, it proposed a template of relevant items to include in national plans. It thus regulates how Member States plan for crises, rather than their substantive decisions, which remain a national prerogative. It also created an obligation for Member States to share information, which is often a delicate matter for Member States. The Electricity Coordination Group (that reunites Member States at the Commission) monitors those plans. In response, the Regulation installed two specific mechanisms to facilitate crisis coordination. It required the adoption of a pre-agreed approach to assistance between neighbouring Member States and it established Regional Coordinating Centres in charge of sharing information and coordinating responses (even though Member States retain decision-making powers).

In sum, despite a distribution of competences that leaves Member States in control of crisis management, this Regulation directs the Commission to regulate how Member States prepare for crises and introduces a strong mandate on Member States to coordinate with one another. Even though it is too early to assess the effectiveness of this regime, it is worth noting that it was developed in response to serious coordination problems during electricity crises and to Member States' reluctance to show solidarity[28] – which recalls issues in the health sector revealed by COVID-19.

2. Shared decision-making with binding coordination mechanisms: food safety

This second domain presents similarities to and differences from both electricity and health. The food safety crisis management regime partly overlaps with the 2013 Decision on health, especially for food-borne crises with human health impacts. Even though the two regimes have developed in parallel since the early twenty-first century and refer to each other, they remain distinct. Notably, the food safety regime is more specific and constraining and attributes decision-making powers to the Commission.

In 2019, the Commission adopted an Implementing Decision (2019/300/EU) "establishing a general plan for crisis management in the field of the safety of food and feed", strengthening and clarifying the previous Decision 2004/478/EC, based on Regulation 178/2002/EC. The food safety regime developed progressively in response to various crises[29] that led to the creation of the European Food Safety Authority (EFSA), a scientific agency tasked with risk assessment. Crisis after crisis, the EFSA expanded its role[30] in crisis preparedness, response and communication.[31]

Surveillance is – as for health – a policy component that is well developed at the EU level, with the presence of alert and information systems under the aegis of the EFSA,

[28] C Egenhofer and C Stroia, "Is Security of Energy Supply Possible without Deeper Cross-Border Market Integration? Lessons from the Cold Spell in South-Eastern Europe" (CEPS 2017) 45.

[29] CK Ansell, C Ansell and D Vogel, *What's the Beef? The Contested Governance of European Food Safety* (Cambridge, MA, MIT Press 2006).

[30] Jordana and Triviño-Salazar, supra, note 6.

[31] "EFSA Procedures for Responding to Urgent Advice Needs" (2017) 14 EFSA Supporting Publications 1228E.

which the 2019 Decision strengthened further. In terms of preparedness, the 2019 Decision is not as prescriptive as for electricity, but it is more so than for health: it does not include templates, but it allows the Commission to audit national preparedness. With regards to response, since food-borne crises relate to the well-functioning of the single market, the Commission has the power to adopt emergency measures and to draw up a crisis management plan. However, Member States may also adopt such measures if necessary. Furthermore, the 2019 Decision set in place an enhanced coordination mechanism with Member States, including the nomination of crisis coordinators, the setting up of a crisis unit chaired by the Commission in charge of adopting and implementing a crisis response strategy and a coordinated communication strategy.

While not exempt from limits,[32] the 2019 Decision on food safety presents several advantages in comparison with the 2013 Decision on health. Rather than relying on a self-assessment by Member States, it allows for an external audit of national plans, even though it does not go as far as harmonising those plans. Although the Commission has more powers to make crisis decisions, the definition of a clear coordination scheme at the EU level, with specific tasks and predefined roles, is more likely to prevent the kind of coordination problems that COVID-19 revealed in the health domain. As for electricity, Decision 2019 has still not been tested. However, the food safety regime relies on experience built over the years that may prove relevant for health.

3. Supranational crisis management regime: banking

The last and less common strategy for EU crisis management consists of transferring crisis management competences to the EU. Such approach solves coordination problems (at least in theory), since EU institutions can decide alone on how to resolve a crisis and retain control over preparedness. Nevertheless, this regime remains infrequent, since Member States are often reluctant to give up their crisis management powers.

One significant example is banking crisis management (for Eurozone countries). The financial crisis of 2008 and the sovereign debt crisis of 2011–2012 blatantly exposed the lack of a common approach to banking failures and its catastrophic effects on states' budgets, their economies and the cohesion of the Eurozone. Consequently, the EU adopted a dual regime of banking crisis management: a less integrated one applying to all EU countries that only aims to harmonise Member States' policies;[33] and an integrated and supranational one that applies only to Eurozone countries. Following the 2012 crisis, Eurozone Member States agreed to create a Banking Union and transfer their financial regulation powers, including those to rescue banks, to the EU. The surveillance of Eurozone banks now falls under the Single Supervisory Board, created in 2013 (Regulation 1024/2013) and located at the European Central Bank.

[32] S Chatzopoulou, NL Eriksson and D Eriksson. "Improving Risk Assessment in the European Food Safety Authority: Lessons from the European Medicines Agency" (2020) 11 Frontiers in Plant Science 349.

[33] Banking Resolution and Recovery Directive (2014/59/EU).

This Board is also in charge of running stress tests to simulate banks' resistance to financial crises. In 2014, the Single Resolution Mechanism Regulation (806/2014/EU) created a new EU agency, the Single Resolution Board, tasked with overseeing banks' resolution plans and making decisions in case of a banking failure for all Eurozone countries.

Such an approach to EU crisis management aims at enhancing the clarity of decision-making and promoting a high degree of harmonisation – even though the distribution of surveillance and preparedness tasks between two different institutions creates some overlaps and confusion.[34] In practice, the regime has revealed many caveats, showing the difficulty for EU institutions to exert crisis management powers that have consequential effects on Member States. Indeed, Member States have retained implementation powers, their own bankruptcy laws and control over small banks. More than once, they have been able to use loopholes to make their own crisis decisions, often with the backing of the Commission.[35] This points to significant drawbacks of the supranational approach to crisis management. Given the diversity of situations Member States face, it does not necessarily reduce the complexity of crisis management. Moreover, these decisions, taken by distant non-elected bureaucracies, often lack legitimacy in the eyes of citizens.[36] In addition to competence issues, such problems should warn against supranationalising public health crisis management.

IV. Strengthening EU coordination mechanisms on serious cross-border health threats

Overall, our description of other crisis management regimes highlights several mechanisms that could structurally improve European countries' responses to serious cross-border health threats. We present below instruments that could contribute to strengthening and clarifying Member States' coordination when a health crisis of a cross-border nature strikes, while preserving their prerogatives and decision-making powers.

1. Reinforcing EU-level risk assessment and epidemiological surveillance capacities

The COVID-19 crisis showed that the ECDC and the HSC did not have sufficient critical epidemiological information on the spread of the virus in Europe. An option to improve EU capacities would be to strengthen the role and funding of the ECDC in order to reinforce its expertise and improve its risk assessment. Several authors advocated for granting the ECDC more funding, together with increased responsibilities for surveillance, preparedness planning and response to infectious diseases.[37] While granting decision-making powers to the ECDC could pose legal challenges,

[34] European Court of Auditors, "The Operational Efficiency of the ECB's Crisis Management for Banks" (Luxembourg, European Court of Auditors 2018).

[35] S Donnelly and IG Asimakopoulos, "Bending and Breaking the Single Resolution Mechanism: The Case of Italy" (2020) 58 JCMS: Journal of Common Market Studies 856.

[36] Cabane and Lodge, supra, note 5.

[37] Anderson et al, supre note 19.

strengthening its advisory role, risk assessment and expertise are options worth pursuing. Despite the difference of competences, the EFSA or the banking agencies could serve as sources of inspiration. We agree with Greer and de Ruijter, who advocate for the creation of an obligation on Member States to improve surveillance and timely reporting of data, as well as to issue binding methodologies for information gathering, which could improve the quality of the data sent by Member States.[38] ECDC capacities to investigate *in situ* and assist Member States in assessing the seriousness of a threat should also be strengthened through increased funding and more staff.

2. Binding coordination of Member States' preparedness planning

Lack of preparedness when COVID-19 hit the EU in March is perhaps the most widely shared diagnosis of the challenges raised by the crisis. While there is a need to supervise preparedness, Article 168 of the TFEU does not allow for a detailed and prescriptive supervision of the substance of plans (such as the number of facemasks or intensive care unit beds). These legal barriers refer to a broader debate within the EU over the value of binding arrangements in comparison to incentive and information-based instruments.[39] In this context, the electricity case suggests an interesting solution by creating binding methodologies and preparedness templates to ensure the convergence of national plans while respecting Member States' domestic competences.

Another major shortcoming of the current system stems from the reliance on self-assessment. Any reform should address this issue by introducing some form of external assessment of national preparedness plans. A recent commission communication on short-term EU health preparedness for COVID-19 outbreaks recommended to introduce stress tests of measures taken by Member States to prepare for subsequent surges of COVID-19.[40] These tests and assessments should be extended and generalised.[41] As in electricity, the HSC could be tasked with monitoring plans, thereby respecting the intergovernmental character of the health regime. Such reform would improve the information available to the HSC and reinforce mutual trust. The ECDC could perform country visits and assess national plans, on which basis the HSC would produce recommendations. Furthermore, such a policy option might have political support, as a French–German proposal put forward a comparable proposal in May 2020.[42]

[38] S Greer and A de Ruijter, "EU Health Law and Policy in and after the COVID-19 Crisis" (2020) 30 European Journal of Public Health 623.

[39] G Majone, "The New European Agencies: Regulation by Information" (1997) 4 Journal of European Public Policy 262.

[40] EU Commission, "Short-term EU health preparedness for COVID-19 outbreaks". Communication from the Commission to the European parliament, the Council the European Economic and Social Committee and the Committee of the Regions (2020).

[41] S Kempeneer, "From One Stress Test to Another: Lessons for Healthcare Reform from the Financial Sector" (2020) European Journal of Risk Regulation.

[42] French–German initiative for the European recovery from the coronavirus crisis (Paris, 18 May 2020) <https://www.diplomatie.gouv.fr/en/coming-to-france/coronavirus-advice-for-foreign-nationals-in-france/coronavirus-statements/article/european-union-french-german-initiative-for-the-european-recovery-from-the>.

3. Binding mechanisms for the coordination of crisis responses based on multi-level decision-making processes

Finally, the EU should supervise to a greater extent the coordination of Member States' responses to cross-border health threats. The 2013 Decision appeared to be too light on states' duties to coordinate in a situation in which human lives are at stakes. However, in the current distribution of competences, it is not conceivable – nor desirable – for a supranational EU authority to make decisions on health crises at the expense of Member States. One solution to this dilemma could be to temporarily extend the HSC coordinating powers when a "State of Emergency" is triggered (Articles 12–14 of the 2013 Decision). Currently, the legal consequences of the State of Emergency are limited to authorising the European Medicine Agency to approve strategic medicine or vaccines quicker than usual. We recommend revising the 2013 Decision to introduce a temporary mechanism of "enhanced coordination" as described in the food safety domain, which would operate from the HSC and where the Member States, with the Commission's technical assistance and the ECDC's expertise, could negotiate binding coordination measures. Enlarging the HSC powers has the virtue of respecting the intergovernmental nature of this domain and the letter of Article 168 by preserving decision-making powers with the Member States while introducing a temporary mechanism of binding coordination in case of a crisis.

Furthermore, the role and functioning of the HSC during crises should be clarified to avoid any confusion, as was seen during COVID-19. The food safety and electricity cases again provide relevant models, with the possibility of setting up crisis units or nominating crisis coordinators within EU institutions and Member States, who could work together continuously and be ready to do so in case of a crisis. This would ease the coordination of national responses and improve communication amongst Member States, the Commission and the ECDC. It might also be relevant to have regional crisis units, as in electricity, as health threats spread spatially and may not affect all Member States.

V. Conclusion

The early stages of the COVID-19 crisis highlighted many limits of EU health crisis management. Progress has been made since then, as coordination significantly improved, together with the recognition of a vital need to adopt coordinated measures and to pool resources to ensure a swift and continuous supply of critical goods. Learning by experience, the EU is now speaking with a more unified voice and progressing towards more integrated instruments. Between the European Recovery plan agreed by national governments on 21 July and a short-term plan to strengthen EU preparedness for future COVID-19 outbreaks released by the Commission on 15 July, there seems to be a political appetite to strengthen the EU's crisis management role. A unique window of opportunity is opening for a more integrated Health Union, as the contributions in this Special Issue discuss. The Health Union could not be achieved without more resources and funding at the EU level, which is at the heart of current discussions around the fourth health programme, the so-called EU4Health Programme. However, there is also an opportunity to structurally reform

the instruments of the health security framework, which at the moment are based on non-binding intergovernmental arrangements. Our analysis of other crisis management regimes led us to suggest reinforcing ECDC powers, creating a mandate to coordinate policies within the HSC and more supervision of national preparedness plans. Such an approach would preserve Member States' decision-making powers while making coordination more binding and the substance of it more detailed.