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Nobody saves himself alone: who decides on health security in the European Union?

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Abstract [En]: The article addresses the changes taking place in the EU with regard to health risk assessment and risk management in relation to communicable diseases. The creation of new European agencies has centralized much of the decision-making process at supranational level, with repercussions on national health administration. It becomes apparent that the EU exerts greater influence on national administrative systems both from the point of view of public policy formation and from a strictly administrative point of view (e.g. with regard to health planning). It also addresses the question of whether the centralization at European level of certain health risk management choices shifts the decision-making responsibility, posing both a problem of democratic legitimacy and of public awareness and respect for these choices.

Titolo: *Nessuno si salva da solo*: chi decide sulla sicurezza sanitaria nell'Unione Europea?
Abstract [It]: L'articolo affronta il tema dei cambiamenti in atto nell'UE per quanto riguarda la valutazione e la gestione del rischio in ambito sanitario in relazione alle malattie trasmissibili. La creazione di nuove agenzie europee ha accentrato gran parte del processo decisionale a livello sovranazionale, con ripercussioni sull'amministrazione sanitaria nazionale. Si pone in luce che l'UE esercita una maggiore influenza sui sistemi amministrativi nazionali sia dal punto di vista della formazione delle politiche pubbliche che da quello strettamente amministrativo (ad esempio con riguardo alla pianificazione in ambito sanitario). Si affronta inoltre la questione se l'accentramento a livello europeo di alcune scelte di gestione del rischio sanitario sposti la responsabilità decisionale ponendo sia un problema di legittimazione democratica che di consapevolezza e rispetto di tali scelte parte dei cittadini.

Keywords: Health security, Communicable deseases, European agencies, European Union administration
Parole chiave: sicurezza sanitaria, malattie trasmissibili, agenzie europee, amministrazione europea

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"Lo único peor que la mala salud es la mala fama"

Gabriel García Márquez

El amor en los tiempos del cólera

Colombia, 1985

* Articolo sottoposto a referaggio.

1. An overview of latest developments in the EU Health Security Administration in the field of communicable diseases[1]

It is a EU common belief that the protection of public health originated, historically, from the very birth of the Nation-State, which takes it upon itself to guarantee public safety, thus affirming (and protecting) its sovereignty[2]. Social rights, and the right to health in particular, on the other hand, are a much more recent conquest, as it is well known, as a result of the (constitutional) revolutions in the second half of the 20th Century. At that historical juncture, the human rights movement reached an international dimension and the first institutionalized international cooperation in health matters was established with the birth of the World Health Organization (WHO). It is not necessary to investigate into the common historical roots of European health systems here, it is sufficient to point out that, despite their differences, European health systems do in fact share a common core, with welfare systems formed after the Second World War and progressively reformed in the 1990s. Even with their relative differences, each State plays a predominant role in the European health systems.

EU Member States have always been very reluctant to shift additional competences in the field of health to the EU level. However, they did so when constrained by a common crisis that could not be tackled by a single country acting alone[3].

The health emergency provoked by the Covid-19 pandemic, fitting into a groove that had already been traced for some time, has definitively undermined the dogma, common to all European countries and supported by the Treaties of the European Union, according to which the promotion and protection of health are tasks that states can carry out in full autonomy. The issue also involves institutional autonomy in relation to both health governance and the organization of national health security[4]. Last March, World Health Organization countries began negotiations on a global agreement on the matter of pandemic prevention, readiness and response, using the "zero draft" as the basis for negotiating an agreement to protect nations and communities from future pandemic emergencies[5]. At the same time, governments are also discussing more than 300 amendments to the International Health Regulations (2005) in an effort

[1] This text reproduces with some modifications the presentation given at the REALaw Forum "*European Administrative Law and the Challenges of Uncertainty*", held in Toledo on 6-7 October 2022, at the Center for European Studies of the University of Castilla-La Mancha.

[2] For a thoughtful historical analysis of the relationship between public power and health protection see G. ROSEN, *A History of Public Health*, John Hopkins University Press, 1st ed., 1958, revised and updated in 1993.

[3] The health crises of the past years and the resulting changes in EU regulation are analyzed by M. FRISCHHUT, *Communicable and Other Infectious Diseases: The EU Perspective,* in *The Oxford Handbook of Comparative Health Law Get access Arrow* edited by D. ORENTLICHER,, T. K. HERVEY, Oxford, 2020, 77; T. HERVEY, A. DE RUIJTER, *The Dynamic Potential of European Union Health Law*, in *European Journal of Risk Regulation*, 2020 11(4), 726.

[4] See M. LOTTINI, *Principio di autonomia istituzionale e pubbliche amministrazioni nel diritto dell'Unione Europea*, Torino, 2017.

[5] See *Countries begin negotiations on global agreement to protect world from future pandemic emergencies,* https://www.who.int/news/item/03-03-2023-countries-begin-negotiations-on-global-agreement-to-protect-world-from-future-pandemic-emergencies.

to make the world safer from communicable diseases and ensuring greater equity in the global response to public health emergencies. The changes in the international organization of health security, although of great interest, will not be addressed here. Instead, the focus will be on the changes in the European administrative organization of health security for the prevention of transmittable diseases risk [6] and the following repercussions on national systems.

In the area of prevention and response to health threats, the existence of an EU Health Administration[7] is now a given, with a weak but growing EU regulatory counterpart[8]. While the EU is facing several institutional (poly)crises[9], a great political attention is undoubtedly focused on countering *cross border* public health threats. After Covid-19 pandemic there is no shortage of EU policies launched for health promotion and security response (among them the *"One health*" approach[10],"*Health in all policies*" and "*EU4Health*"). Nevertheless, compared to other policy areas, the EU health sector is exceptionally fragmented and pluralistic. As a result, prevention and response to *cross-border* health threats implies completely new organizational and administrative procedures in the EU. Some of the main peculiarities can be highlighted immediately.

Despite the fact that in the field of health the EU has very "weak" competences and its task is mainly to support the States, to this date, out of forty-two EU agencies, at least six have direct and specific

[6] As highlighted by the new Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing decision no 1082/2013/EU discussed *infra*, unlike communicable diseases, the surveillance of which at Union level is carried out on an ongoing basis by the ECDC, other serious cross-border health threats do not currently require systematic monitoring by Union agencies and bodies. A *risk-based* approach, where monitoring is carried out by Member States' monitoring systems and information is exchanged through the EWRS, is therefore more appropriate for these threats.

[7] Although this expression is not used in EU regulation (which prefer using just "*European Health Union*"), we will use this to refer comprehensively to the EU *governance* operating in health matters, including EU Agencies and all the other bodies involved; for an analysis of the development of the European health *governance* see, M.L. FLEAR, *Governing Public Health*, Hart Publishing, 2018; Id., *Reframing public health governance: From Risk to Citizenship and Participation*, in EU Citizenship and Federalism edited by D. KOCHENOV, 2017, 294; Id., *"Together for health? How EU governance of health undermines active biological citizenship*, in *Winsconsin International Law Journal*, 2008-2009, 3, 867.

[8] The objectives of the EU Institutions are manifold and well represented by the principle of "*Health in all policies*", which outlines a complex framework that is difficult to relate to the EU's limited competence in health, see E. RUIZ CAIRÓ, *The promotion of public health in EU external relations,* Geneve, 2021, 50 ss. On the stages and characteristics of the evolutionary process of EU administrative organisation see C. FRANCHINI, *Le fasi e i caratteri del processo evolutivo dell'organizzazione amministrativa europea*, in *Riv. it. dir, pubb. com.*, 2017, 2, 375; G. DELLA CANANEA, C. FRANCHINI, *I principi dell'amministrazione europea,* Torino, 2017.

[9] The wave of different types of crises in the EU was significantly described as *"polycrisis"* by Jean-Claude Juncker in 2016 (financial crisis, migratory flows, attacks on the Rule of Law from the Est Europe and more recently war in Ukraine, Covid-19 pandemic fight), for an analysis, see J. ZEITLIN, F. NICOLI, *The European Union beyond the polycrisis?,* London, 2020; see also N. COHEN, A. DOOTALIEV, eds., *European Integration and Disintegration*, essays from the new generation of thinkers, London, 2022; A. VON BOGDANDY, *European Democracy: A Reconstruction through Dismantling Misconceptions* (January 21, 2022). Max Planck Institute for Comparative Public Law & International Law (MPIL) Research Paper No. 2022-02, Forthcoming in: ELTE Law Journal (2022).

[10] See Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027; on the topic see F. APERIO BELLA, (edited by), *One health: la tutela della salute oltre i confini nazionali e disciplinari*. *Per un approccio olistico alla salute umana, animale e ambientale,* Naples, 2022.

competences in the field of health[11] and at least three have competences affecting health protection[12]. We can now distinguish between a "first generation" of health EU agencies established in the 1990s, such as the European Agency for Safety, Health and Work and the European Environment Agency (1994), the European Medicine Agencies (1995), and some "second generation" agencies established since 2000, such as the European Centre for Disease Control and Prevention (2005) and the European Food Safety Agency (2002). To these must be added the "third-generation" agencies established in the last two years, such as the European Authority for Health Emergency Readiness and Response and the European Health and Digital Executive Agency[13] (2021).

Increasing the number of agencies and strengthening EU health governance goes *hand in hand* with the proposal to amend Decision n. 1082/2013/EU on serious *cross-border* threats to health by introducing a new *Regulation on serious cross-border threats to health* (hereafter *Regulation*)[14]. This is an *epoch-making change* for EU regulation that aims to effectively implement certain provisions of the Treaties (Art. 168(5)) that have hitherto remained quietly underused compared to the purposes for which they were conceived, while preserving the normal functioning of the single market in the event of serious *cross-border* threats to health. The reasons for amending Decision 1082/2013 had already transpired in the past: first the European Commission (EC) in 2015[15], then the European Court of Auditors in 2016[16] clearly pointed out serious shortcomings in the actions of the European Institutions and Member States in its implementation without, however, achieving any effect. Early lessons learnt from Covid-19 have shown that the current system has not ensured an optimal response at EU level to the pandemic[17]. As highlighted in the Proposal of the new *Regulation* the current health security arrangements provide a limited legal framework for EU level coordination, based essentially on the *Early Warning and Response System* (EWRS) and the exchange

[11] The European Medicines Agency ("EMA"), the European Centre for Disease Control and Prevention ("ECDC"), the European Food Safety Agency ("EFSA"), the European Health and Digital Executive Agency (HaDEA) and the European Authority for Health Emergency Preparedness and Response (HERA), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

[12] The European Chemicals Agency ("ECA"), the European Environment Agency ("EEA"), the European Agency for Safety, Health and Work ("EASHW").

[13] From 1 April 2021, HaDEA has actually incorporated the health expertise of the Executive Agency for Consumers, Health, Agriculture and Food Safety (CHAFEA).

[14] See the *Regulation of the European parliament and of the Council on serious cross-border threats to health and repealing decision no 1082/2013/EU*repealing, in https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=consil:PE_40_2022_REV_1; the EU Commission Proposal passed Parliament's approval with several amendments (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020PC0727).

[15] See the 1st EC Report on the implementation of Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious *cross-border* threats to health and repealing Decision No 2119/98/EC, Brussels, 7.12.2015, COM(2015) 617 final in https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52015DC0617&from=en.

[16] See EU Court of Auditors, Special report no 28/2016: *Dealing with serious cross-border threats to health in the EU: important steps taken but more needs to be done*, in https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=40126.

[17] On the functioning of the Italian system see A. IANNUZZI, G. PISTORIO (eds.), *La gestione dell'emergenza sanitaria tra diritto e tecnica*, Naples, 2022.

of information and cooperation within the *Health Security Committee* (HSC). The new *Regulation* expands the legal mandate of the European Centre for Disease Control and Prevention[18] ("ECDC") to reinforce its too limited powers[19]. ECDC will have to coordinate its actions with the new agencies with specific tasks in the field of health: the *European Public Health Emergency Preparedness and Response Authority* ("HERA"), established formally as an administrative service, but with a very special structure to perform particular functions of *risk management* preventing and addressing health emergencies and information coordination between States and the *European Executive Agency for Health and Digital Affairs* ("HaDEA") that implements most of "*EU4Health*", the largest plan to boost health around the EU[20]. The EC also proposed on the 11th of November 2020 to reinforce the mandate of the European Medicines Agency (EMA), so in 2022 the powers of the EMA have been strengthened[21]. In 2021, the EU strengthened the *Emergency Response Coordination Centre* (ERCC) with enhanced operational, analytical, monitoring, information management and communication capabilities. It's also clear that the EC wants to assume autonomy from WHO in response to *cross-border* emergencies to allow an independent and quicker EU response.

[18] The ECDC, created by Regulation 851/2004 is an agency whose main missions are epidemiological surveillance, early warning and response. The ECDC manages the SAPR and coordinates with other agencies such as the EMA. It is also responsible for providing scientific advice - at the request of the Commission, the European Parliament or a Member State on its own initiative; providing technical assistance to Member States and third countries; and support and development actions to prepare for new health threats. Since 2004, the ECDC has managed and coordinated the European monitoring network. ECDC's scientific expertise, which is mainly reflected in the adoption of reports of a technical nature, accessible on its dedicated website, has probably not been sufficient to make it the sole scientific reference within COVID-19, as evidenced by the establishment during the pandemic of a "*COVID-19 Advisory Group*". To this expert group, composed of epidemiologists and virologists from several member states, was given the task of developing EU guidelines for coordinated, science-based risk management measures; critically on the role of ECDC and WHO during the pandemic see, B. MARCHETTI, *Il ruolo della OMS e del Centro europeo per la prevenzione e il controllo delle malattie nell'emergenza sanitaria: servono più o meno poteri oltre lo Stato?,* in *Biopolitica, pandemia e democrazia. Rule of law nella società digitale*, I, Problemi di governo, ed. by A. PAJNO, L. VIOLANTE, Bologna, 2021, 199.

[19] The ECDC has a specific mandate in the area of *communicable disease* threats but no mandate in the area of other health threats, nor on the procurement, development or production of medical countermeasures. In November 2020, the EU Commission presented a proposal to expand the legal mandate of ECDC. First, a draft Regulation changing ECDC's current Founding Regulation was announced, which contains changes that reinforce the ECDC mandate so that the Centre may support Member States and the Commission in the following areas: epidemiological surveillance via integrated systems enabling real-time surveillance; preparedness and response planning, reporting based on defined indicators; provision of non-binding recommendations and options for risk management; capacity to mobilise and deploy a EU Health Task Force to assist outbreak/emergency response in Member States and in third countries; build a network of EU reference laboratories and a network for substances of human origin. After a series of interinstitutional negotiations in the so-called trilogues between the EU Commission, the EU Parliament and the Council of the EU, on 29th of November 2021, the European Parliament and the Council reached a political agreement on a reinforced role for ECDC. The formal adoption of the changes to the ECDC Founding Regulation is foreseen to happen once the agreement on proposal on the Regulation on Serious Cross Border Threats to Health.

[20] HaDEA was established on 16 February 2021 to allow for all necessary administrative preparations before its operational kick off on 1 April 2021.

[21] See Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, available here http://data.europa.eu/eli/reg/2022/123/oj.

From this rapid overview, a complex and innovative reality emerges. The aim of this article is to analyze the main organizational and procedural transformations affecting the EU health administration.

First, it will be analyzed what the EU have done during the Covid-19 pandemic and why such major regulatory changes were necessary as a consequence (paragraphs 2 and 3). The procedural aspects emerging from the new *Regulation* will then be examined to find out how they have revised the health *risk assessment* and response. (paragraph 4). It will also be analyzed how these changes relate to national health administrations (paragraph 5). The last point concerns the final effects on administrative cooperation in the field of health security (which takes on a more centralized dimension in the EU) and the responsibility for decisions on new health threats, which seems to fall more on the EU (on the EC and its agencies) than on member state governments (paragraph 6).

2. The "weak" role played by the EU during the Covid-19 pandemic

At the beginning of the Covid-19 pandemic, the" weak" competences attributed to the EU by Article 168 TFEU[22] clashed with the urgency of the EU intervention, making it necessary to use international law[23] or other Treaty dispositions as legal bases[24]. The lack of a proper European protocol has led to great discrepancies within an epidemiological framework that has not been linear throughout the EU, but has followed different timelines and responses depending on the decisions of the governments of each state.

[22] According to the Treaty on the Functioning of the EU (TFEU), the EU institutions have limited powers in the field of public health. Article 168(1) TFEU allows them to "support, coordinate or supplement" EU Member States, see S. GARBEN, *Article 168*, in M. KELLERBAUER, M, KLAMERT, J. TOMKIN (eds), *The EU Treaties and the Charter of Fundamental Rights: A Commentary* (New York, 2019; online edn, Oxford Academic), https://doi.org/10.1093/oso/9780198759393.003.278, accessed 24 Sept. 2022; As noted by M. FRISCHHUT, *Communicable and Other Infectious Diseases: The EU Perspective,* an example of a "strong" competence is TFEU, art 168 para 4. According to this provision, the EU has a "shared competence" and can also legislate in the context of organs and substances of human origin, blood and blood derivatives (lit a), and measures in the veterinary and phytosanitary fields (lit b), as well as medicinal products and devices for medical use (lit c). The second category (lit b) has been important for the context of Bovine Spongiform Encephalopathy because the EU has a health-related competence which is independent from the agricultural competence.

[23] As L. TRIBESS, E-M. BÖNING, *Better Safe than Sorry: Human Rights Obligations for the Prevention of Pandemics,* in *Max Planck Institute for Comparative Public Law & International Law* (MPIL) *Research Paper* No. 2022-08, this is a duty to intervene that originates directly from international law.

[24] An example is the Regulation on Covid-19 certificates (see the "*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*") which, although its main objective is to guarantee health safety in the Union, has as its legal basis Article 21 on free movement. Also in the past, most EU legislation relevant to Non-communicable Disease Prevention has been adopted on the basis of Article 114 of the TFEU, which empowers the EU to adopt common rules for the establishment and the functioning of the internal market, see A. GARDE, *The Lack of Coherence in the European Union's Approach to Noncommunicable Disease Prevention*, in The Oxford Handbook of Comparative Health Law Get access Arrow, edited by D. ORENTLICHER, T. K. HERVEY, Oxford, 2020, 142; V. DELHOMME, *Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health*, in *European Journal of Risk Regulation*, 11 (2020), 747.

Although the EU has no competence to take preparedness measures, it can at least coordinate the Member States and the EC in a reciprocal consult within the *Health Security Committee*.

The EU was able to rely on Decision 1082/2013/EU, which is the only piece of legislation related to serious *cross-border* health threats that had so far had limited use (mainly in 2014 as a brake on Ebola from South Africa). This meant that during the Covid-19 pandemic, the EU's main role was limited to the *exchange of information,* the *European Surveillance System* (TESSy[25]) and the *joint procurement* of medical countermeasures[26] (e.g. vaccines). According to Decision 1028/2013/EU one of the actors that play (or should have played) the main role in coordinating the European response by collecting data on contagions was undoubtedly the ECDC, whose duty is to perform *risk assessments*, governing the *epidemiological surveillance* network and provide EU Member States with guidelines and recommendations. Through the *epidemiological surveillance* network, national authorities communicate with to each other data and information on transmittable diseases and related special health problems, as well as information on the progression of epidemic situations. By means of the EWRS, on the other hand, Member States and the EC communicate the appearance or development of a serious *cross-border* health threat that causes or may cause high morbidity or mortality in humans and whose scope is increasing or may increase rapidly. Together with the alert, national authorities communicate information useful to prepare a coordinated response. Based on this information, the ECDC, the European Food Safety Authority (EFSA) or other relevant agencies prepare a *risk assessment* analysis which, together with national data, will be useful in coordinating a joint response. While the ECDC had no effective intervention tools or decision-making powers of any kind, it was therefore the *Health Security Committee* (HSC) that had the highest responsibility for the coordination among EU[27]. The HSC, composed of representatives of the Member States and chaired by a representative of the EC, manages the exchange of information between the Member States and the EC and coordinates, in liaison with the EC, Member States' preparedness and response for serious *cross-border* health threats. To this end, national authorities also share their best practices and experiences. The design of the national response to the emergency situation therefore remains at the discretion of every Member State. Anyway when a Member State intends to adopt or does adopt emergency public health measures to fight a serious *cross-border* threat to health, it informs and consults other Member States and the EC about the nature, the subject and the scope of these measures[28]. Frequent daily HSC meetings were held during the peak of the pandemic. The HSC was the key body for coordinating the response in the EU. It served as a platform to share information on countermeasures

[25] The European Surveillance System (TESSy) is a database hosted at ECDC: ecdc.europa.eu/en/publications-data/european-surveillance-system-tessy.
[26] See art. 5 of the Decision 1028/2013/EU on "*Joint procurement of medical countermeasures*".
[27] See art. 17 of the Decision 1028/2013/EU.
[28] See art. 11 par. 9 of the Decision 1028/2013/EU.

(e.g. vaccination strategies) and to coordinate communication to health professionals and EU citizens. Nevertheless, the exchange of information did not allow a real coordination. The consistency between ECDC scientific studies and national instances that could have led to the sharing of common measures to tackle the pandemic within the EU was not achieved.

One of the legal tool most useful was undoubtedly the one of civil protection cooperation, notably the *Union Civil Protection Mechanism* (UCPM) and the *Emergency Response Coordination Centre* (ERCC). Through the Mechanism, the EU helps coordinate and finance the delivery of vaccines, medical and protective equipment and other material across Europe and the world, to countries that seek assistance. Another EU instrument, the *Joint Procurement Agreement*, was also used to strengthen preparedness. The EU has played a strong role in the marketing of vaccines, which, according to current EU legislation, goes through a recommendation by the EMA, which assesses the safety, efficacy and quality of the vaccine, on the basis of which the European Commission can proceed to authorise marketing in the EU market, after consulting the Member States, which must give a favorable opinion by qualified majority. EU legislation - in particular Article 14-*bis* of Regulation (EC) n. 726/2004 provides for a specific regulatory instrument to allow the rapid availability of medicinal products, to be used in emergency situations, since in such situations the *"conditional marketing authorization"* (CMA) procedure is specifically designed to allow authorization as quickly as possible, as soon as sufficient data are available, while providing a solid framework for safety, guarantees and post-authorization controls[29].

3. Developments in the response to *cross-border health threats* after the Covid-19 pandemic

From the point of view of the citizens the weak role of the EU created a climate of mistrust in the European institutions which were therefore spurred to react[30]. To overcome the coordination problems that emerged during the Covid-19 pandemic, not only have the tools and techniques to ensure EU cooperation[31] for the prevention and management of health emergencies been considerably strengthened, but it has also been decided to create two new agencies[32] and to give the existing ones (in particular EMA

[29] In this procedure there is a *partial overlap* of the clinical trial phases, which in the normal procedure are sequential, and whereby the start of the next phase is shortly after the start of the previous phase.

[30] An OECD study shows that during the pandemic, trust in European institutions decreased while trust in national authorities increased: see OECD study *Building Trust to Reinforce Democracy Main Findings from the 2021 OECD Survey on Drivers of Trust in Public Institution,* in https://doi.org/10.1787/b7d1e606-en.

[31] See L. DE LUCIA, *Strumenti di cooperazione per l'esecuzione del diritto europeo*, in L'amministrazione europea e le sue regole, ed. by L. DE LUCIA, B. MARCHETTI, Bologna, 2005, 171.

[32] About "agencification" see E. CHITI, *The agencification process and the evolution of the EU administrative system*, in *The evolution of EU LAW*, III edition 2021 Oxford edited by P. CRAIG G. DE BÙRCA, 123 ss; Id., Agenzie Europee, in Dizionario di Diritto Pubblico, Milano, edited by S. Cassese, 2006, 164; Id., *Decentralised Integration as a New Model of Joint Exercise of Community Functions: A Legal Analysis of European Agencies*, in *European Public Law Review*, 2003, 1267; E. CHITI – C. FRANCHINI, *L'integrazione Amministrativa Europea*, Padova, 2003, 97; J. ZILLER, *L'Autorité administrative dans l'Union européenne*, in *EUI Working Paper LAW*, 2004-14, 15-16; M. CONTICELLI, M. DE BELLIS, *Proceduralization of EU Agencies:*

and ECDC) a long-term structure with stronger powers. Also HSC was strengthened. The result has been a strong centralization of *cross border* health threat assessment at EU level where overlapping roles emerge. On the 1st of April 2021, the *European Digital and Health Executive Agency* (HaDEA[33]) started to work with the specific task of implementing the European Health Programme "*EU4Health*" (2021-2027). The aim of the program is to strengthen national health systems through the better use of data, the development of digital tools and services and the implementation of EU health legislation. Subsequently, on the 16th of September 2021, the *European Authority for Health Emergency Preparedness and Response* (HERA) was established as an internal structure within the EC[34]. While the HaDEA will mainly deal with coordinating and integrating Member States' health systems at a general level, HERA is tasked with intervening in actions that Member States cannot efficiently and effectively tackle alone, regarding preparedness, management and response to *cross-border* health threats. HERA, together with the Member States, yearly identifies three specific high impact health threats to ensure preparedness and response, in particular by addressing possible gaps in the availability and accessibility of medical countermeasures (MCMs)[35]. In the *Work Plan* for 2022, HERA has identified six main tasks relating to *cross border* threats preparedness[36]. The authority goal is not only to strengthen health security, but also to take on the role of a privileged observer of technological innovation in health in Europe and will thus be able to support the European institutions in the implementation of health policies[37].

Theory and Practice, in EU Executive Governance: Agencies and Procedures, Torino, 2019, 1 ss; M. SAVINO, *Le agenzie europee,* in *L'amministrazione europea e le sue regole,* cit., 56.

[33] From 1 April 2021, HaDEA has actually incorporated the health expertise of the Executive Agency for Consumers, Health, Agriculture and Food Safety (CHAFEA).

[34] On 16th of September 2021 HERA was established by an EC Decision "*Establishing the Health Emergency Preparedness and Response Authority*" available here: https://health.ec.europa.eu/publications/commission-decision-establishing-health-emergency-preparedness-and-response-authority-hera_en

[35] On 8 July 2022, HERA released an initial factsheet in which it identified the three HERA top 3 priority health threats on which to focus its action and that of the Member States, see HERA factsheet - HEALTH UNION: Identifying top 3 priority health threats, available here: https://health.ec.europa.eu/publications/hera-factsheet-health-union-identifying-top-3-priority-health-threats_en#details.

[36] See the HERA work plan 2022, available here: https://health.ec.europa.eu/publications/hera-work-plan-2022_en. The six tasks are the following: 1. Threat assessment and intelligence gathering; 2. Promoting advanced R&D of medical countermeasures and related technologies; 3. Addressing market challenges and failures and enhancing the Union's open strategic autonomy; 4. Ensuring the provision of medical countermeasures; 5. Strengthening knowledge and skills; 6. International dimension. A total contribution of EUR 1.3 billion from the EU budget is allocated to HERA in 2022 for preparedness activities. The budget of HERA for 2022 foresees contributions from EU4Health (EUR 275 million), Horizon Europe (EUR 395 million) and UCPM/rescEU EUR 630 million). The work plan considers ongoing or planned calls under Horizon Europe and rescEU in 2022, the exact final allocations depend on the projects that will be selected in the open calls.

[37] HERA, should strengthen cooperation and activities with the Member States, the ECDC, EMA and other agencies or bodies, research infrastructures and the WHO to improve, through the *One Health approach*, the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance, and other major non-communicable diseases.

Looking at the structure, HERA's internal division follows that of the ECDC[38]: (a) a Director (b) (b) a *Board* (c) an *Advisory Forum* plus a (d) *Coordination Committee*[39]. The HERA *Board* is composed of one high-level representative from each Member State, appointed by the EC on the basis of nominations from the competent national authorities[40]. All members of the *Board* are appointed for a two-year term, renewable once. A member of the ECDC, of the European Parliament and (but only previous invitation) members of other EU agencies may participate in as "observers". The Board assists and advises the EC in the formulation of strategic decisions to develop close cooperation with the Member States on *cross-border* health threats and emergencies preparedness and response, research and innovation and industrial strategy in the field of medical countermeasures. It may issue opinions on topics such as measures required for the response to *cross border* health crises and the procurement of medical supplies. Experts may also be heard during the reunion of the Board on the grounds of specific needs.

As it is the case with the ECDC, HERA will also have the task of periodically bringing together European expertise for the continuous acquisition and exchange of relevant scientific information on advances in medical science through the *Advisory Forum*[41]. While the ECDC *Advisory Forum* deals with the exchange of information on health threats and the consistency of scientific responses provided by states, HERA *Advisory Forum* provides a mechanism for the *exchange of information* on preparedness and response in the field of medical countermeasures and as well as in the pooling of knowledge.

In the new *Regulation* the relationship between the Hera *Board* and the new role of the HSC is not clear. The two bodies seem to overlap. The *Regulation* contains provisions to reinforce the role of the HSC that will be composed of representatives of the Member States as well, but it will be split in two working levels: (a) a *senior level working group* for regular discussions on serious cross-border threats to health and for the adoption of opinions and guidance; and (b) *technical working groups* to discuss specific topics if necessary. Responsibilities are added to the HSC with regard to the adoption of guidelines and opinions to better support Member States in the prevention and control of serious *cross-border* threats to health, and ensure better coordination between the Member States to address these threats. Representatives of

[38] According to art. 13 of the Regulation EC No 85/2004 of the European Parliament and of the Council of 21 april 2004 establishing a European Centre for disease prevention and control the ECDC has a Director, a Board and an Advisory Forum composed of technically competent representatives of the member states.

[39] The Coordination Committee provides political guidance on the planning and implementation of HERA's tasks, without prejudice to the prerogatives of the College of Commissioners. The Coordination Committee is composed of: (a) the Vice-President of the Commission responsible for Health; (b) the Member of the Commission responsible for Health; and (c) the Members of the Commission responsible for Internal Market, Innovation and Research and Crisis Management

[40] See art. 6 of EC Decision "*Establishing the Health Emergency Preparedness and Response Authority*", cit..

[41] The HERA Forum (like the ECDC' Forum) is composed of members from technically competent bodies designated by each Member State. Members of the Forum shall not be members of the HERA Board. The Forum supports the HERA Board in providing scientific and technical advice.

the European Parliament or agencies are allowed to participate as observers in HSC meetings as well as in HERA *board* meetings.

There are, however, some unchanged elements. As it has been so far, apart from the transmittable diseases, whose surveillance at EU level will permanently carried out by the ECDC, other potentially serious *cross-border* health threats will not be monitored by the new EU agencies[42]. The EU will maintain, as foreseen in the 2013 Decision, a *risk-based approach*, in which monitoring will be carried out by Member States and available information will be exchanged through the new networks and the EWRS.

4. Risk assessment and risk management in *cross-border* health risk procedures and countermeasures against Monkeypox (MPX)

It seems that a shift from *an informational cooperation* to a stronger *institutional cooperation* governed mainly by the EC and EU agencies[43] is taking place in the area of tackling *cross border* health threats. An example may help to understand this matter very clearly. During the acute phase of the Covid-19 pandemic, Italy (especially Lombardy, which was the most affected region) did not have enough intensive care unit hospitals. Thanks to the exchange of information on the infection situation between the States, many Italian patients were accommodated in German facilities with the help of the German embassy in Italy, which coordinated the movements[44]. During the work on the new Regulation, the European Parliament had even proposed that when declaring a health emergency, the EC and in particular HERA should guarantee "*the number of accommodation facilities in hospitals in the Member States, as well as the number of available accommodation units in intensive care units in the Member States, are known, for the purpose of cross-border movement of patients*[45]". The final version of the Regulation did not accept this Proposal, but the *Regulation* strengthens the role of the EU in both *risk assessment* (which is a competence of the scientific experts and thus of the agencies) and *risk management* (mainly a prerogative of the Member States[46]) by blurring the borderline.

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[42] Nevertheless, the ECDC should have the ability to monitor the impact of communicable diseases on major non-communicable diseases, including mental diseases, assessing the continuity of screening, diagnosis, monitoring, treatment and care in the healthcare system, in coordination with existing data sets, tools and registers.

[43] See E. SCHMIDT-AßMANN, *Introduction: European composite administration and the role of European administrative law,* in *The European composite administration,* ed. by O. Jansen and B. Schöndorf-Haubold, Cambridge, 2011, 5; H.C.H. HOFMANN, *Information and Administration*, in *Administrative Law and Policy of the European Union*, edited by H. C.H. Hofmann, G. C. Rowe, A. H. Türk, Oxford, 2011, 412; ID., *Information Exchange in the European Administrative Union* in *European Public Law* (2014), 2014(1), 65; On the "polycentric" relations between national and European authorities, see C. FRANCHINI, *Le relazioni tra le agenzie europee e le autorità amministrative nazionali*, in *Riv. it. dir. com.*, 1997, 1, 15.

[44] See the Document issue by the German Ambassy available here: https://italien.diplo.de/blob/2343834/5b32fff640751d08cc13ee7ae8bdfc9c/humanitaeren-unterstuetzungsleistungen-fuer-italien-data.pdf.

[45] See Amendment 32 in the *Draft of Proposal*, available here: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_15202_2021_INIT.

[46] Risk management comprises a broad range of tools (e.g., vaccination, isolation and quarantine, travel restrictions) which mainly fall within the competences of Member States.

One of the most interesting aspects of the new *Regulation* is undoubtedly the composite procedure for responding to *cross border* health crises, which requires vertical and horizontal coordination between the EC, agencies and States[47]. Once the notification of the threat has been received, it is the task of EU agencies to carry out the *risk assessment*. According to art. 20 of the *Regulation* the risk assessment will be firstly done by agencies according to their respective areas of expertise (ECDC, EFSA, ECHA, EEA EMCDDA)[48]. At the request of the agency carrying out the *risk assessment*, the other agencies must provide all the relevant information and data at their disposal without delay. The EC will make the *risk assessment* available to the national competent authorities promptly through the EWRS and to the HSC, and, if appropriate, through linked alert systems[49]. The *Regulation* says nothing about the risk threshold that is required for the declaration of an emergency at EU level (Art. 23), but it is clear that in the event of scientific uncertainty about the existence or extent of risks to human health or the environment, the precautionary principle allows the EC to take protective measures without having to wait for the reality and severity of such risks to become fully apparent or for adverse health effects to materialize.

After having carried out a scientific evaluation/*risk assessment* in such a way that potential risks are set out and uncertainties are identified, the issue of adopting *risk management* measures comes up. Where a Member State intends to adopt public health measures to combat a serious *cross border* threat to health, it shall, before adopting or ceasing those measures, inform, consult and coordinate with the other Member States, in particular neighboring States, with the EC, on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary[50]. The EC may complement the action of the States through the adoption of *recommendations* on common temporary public health measures. To support the decision making process on the formal recognition of a public health emergency at Union level, the Commission shall establish an *Advisory Committee* on public health emergencies composed by independent experts. The *recommendation* shall be based on the recommendations of the ECDC and the WHO, or of other relevant agencies or bodies, or an *Advisory Committee*. It's not clear if, in case a Member State decides not to follow a recommendation, it must state its reasons for doing so.

The role of HERA is not yet clear in the *Regulation*. The authority (as yet not included among those competent to carry out a *risk assessment*) will have mainly an executive task in *risk management* procedures. HERA's role has emerged in the case of monkeypox (MPX). Cases are registered through a surveillance

[47] See H.C.H. HOFMANN, *Composite decision making procedures in EU administrative law,* in *Legal Challenges in EU Administrative Law*, ed. by H.C.H. HOFMANN, A. Türk, Cheltenham, 2010, 136.
[48] See art. 20 par. 1 of the *Regulation*.
[49] See art. 20 par. 3 of the *Regulation*.
[50] See art. 21 of the *Regulation*.

system of the ECDC and the WHO working independently, which then produce a single joint-bulletin[51]. In the EU the risk *assessment* was done using a stochastic mathematical model jointly developed by ECDC and the HERA in order to evaluate vaccination strategies as epidemic response measures. Information is collected by the ECDC. Then, HaDEA and HERA concluded a contract with the company (Bavarian Nordic) to purchase 109.090 doses of their third generation vaccines (*Jynneos*) (already approved by the Food and Drug Administration in the United States of America) in response to the current MPX outbreaks[52]. As the number of cases continued to grow, this agreement will make vaccines rapidly available to all EU Member States, Norway and Iceland. Following the HERA's decision *Jynneos* has also been authorized in Italy after acquiring the positive opinion of the Italian drug agency[53] (AIFA).

5. EU impact on National health planning

A great impact with respect to the health autonomy of the Member States of the new European regulation is undoubtedly to be found in the obligations to adopt new specific *national plans* for risk prevention coordinated at EU level and the reinforced surveillance powers of the Commission and the ECDC. Every three years, the ECDC shall assess the Member States state of implementation of the national plans and their relation with the EU plan. Such assessments shall be based on a set of agreed indicators and implemented in cooperation with the relevant Union agencies, aiming at the assessment of prevention, preparedness and response planning at national level. The ECDC shall present to the Member States and the Commission recommendations of the examinations addressed to Member States, taking into account national respective circumstances. Member States shall, if applicable, present to the Commission and the ECDC, in a timely manner, and anyway within nine months of receipt of its conclusions, an action plan addressing the proposed recommendations of the assessment with the corresponding recommended actions and milestones. Nevertheless, in order to ensure the interoperability of national plans with the Union plan, harmonization of laws and regulations, which is excluded by Article 168(5) TFEU, should be necessary.

[51] See the Joint ECDC-WHO Regional Office for Europe Monkeypox Surveillance Bulletin: https://www.who.int/europe/emergencies/situations/monkeypox/situation-reports.

[52] See the official HERA press release available here: https://ec.europa.eu/commission/presscorner/detail/en/IP_22_3674; Then HERA has secured an additional 170,920 doses of Bavarian Nordic's 3rd generation vaccine to respond to the ongoing monkeypox outbreak and to meet the more immediate needs. This brings the total number of doses directly purchased by the EU to 334,540 for Member States.

[53] See Decree adopted on the 1st of July 2022 by the Ministry of Health, available here: www.gazzettaufficiale.it/eli/id/2022/07/20/22A04121/sg.

6. Closing remarks

In conclusion a main point stands out. In the field of communicable diseases the EU has built a highly complex system of governance whose powers go beyond the narrow competences assigned by the Treaties. The space available makes it necessary to highlight a few considerations in a nutshell. All the changes highlighted lead (at least) to four effects:

(a) decisions taken on the response to *cross-border* threats are made by enhancing the role of agencies (and experts) in the EU[54]. Member States, the EC, and agencies, applying the *One Health* approach, will use recognized public health organizations and experts, both in the area of transmittable and major non-transmittable diseases, and other stakeholders in all sectors, available to assist in Union responses to health threats. These experts and stakeholders, including civil society organizations, will be structurally involved in all crisis response activities and will contribute to decision-making processes. While this is true for transmittable diseases, in the case of non-transmittable diseases the results of the evaluations are not explicitly binding for Member States, but there is an element of "peer pressure" which may provoke Member States into action when they would not have acted on these issues of their own accord. In the field of *cross-border* health threats for transmittable diseases, it is still unclear to what extent risk assessments actually become binding, leaving only risk management to the autonomy of states (always to be carried out with ever-stronger EU coordination, in accordance with EC recommendations and as evidenced by the creation of HERA);

(b) a greater influence on national administrative systems both from the point of view of public policy formation and from a strictly administrative point of view (planning); (c) a shift of responsibility (also from the point of view of European citizens) that centralizes certain risk management choices at EU level (such as the medical countermeasures to be taken). These last two changes (b and c) should not necessarily be read as a weakening of national institutional autonomy with respect to health security decisions; in fact, it should be emphasized that a system of shared responsibility enhances the effectiveness of each Member State's security. Nonetheless, there is a real need for more shared decision-making at the national level in relation to the choices made by EU agencies. This can be achieved by promoting greater transparency of decision-making paths and broader participation of all levels of

[54] For an analysis of the role of experts in the area of health with respect to democratic legitimacy see T. HERVEY, A. DE RUIJTER, *The Dynamic Potential of European Union Health Law*, cit. 2020, 726; M.L. FLEAR, *Governing Public Health*, Hart Publishing, 2018; Id., *Reframing public health governance: From Risk to Citizenship and Participation*, in EU Citizenship and Federalism edited by D. KOCHENOV, 2017, 294.

government in technical discussions with EU agencies and in the follow-up of interim results to be achieved[55];

(d) lastly, a central aspect that cannot be fully addressed here, the lack of awareness (or stressed indifference[56]) of European citizens about the decision-making processes of the European institutions in the field of health security, which is evidently frustrated by all these quick changes[57].

[55] On how decisions can be made fully informed, but at the same time democratically legitimised in purely or predominantly "expertcratic" contexts see L. MÜNKLER, *Expertokratie Zwischen Herrschaft kraft Wissens und politischem Dezisionismus*, Tübingen, 2020.

[56] On "indifference" as a component of EU legitimacy see C. DOBLER, *Winning minds not hearts? Citizens emotions and European integration,* in C. LORD - P. BURSENS - D. DE BIÈVRE - J. TRONDAL - R. A. WESSEL (eds.) *The Politics of Legitimation in the European Union: Legitimacy Recovered?*, London, 2022, 56.

[57] On the problems of democratic participation in EU decision-making processes, see D. FERRI, "*Participation in EU Governance: A 'Multi-Level' Perspective and a 'Multifold' Approach*", in C. FRAENKEL-HAEBERLE, S. KROPP, F. PALERMO & K.P. SOMMERMANN, Citizen Participation in Multi-Level Democracies, Brill Nijhoff, 2015. 348, 363; C. LORD, *The Many Actors of Direct and Indirect Legitimation,* in *The Politics of Legitimation*, cit., 300.