

Covid-19, a “Soft” Regulatory state approach and the Spanish Experience*

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1. Introduction

The coronavirus (Covid-19) crisis has put a spotlight on the relationship between and the respective roles of politicians and experts. Governments around the world have been forced to make complex decisions regarding health care, the movement of citizens at both international and subnational levels, access to education, the use of public space, the closure of businesses and exceptional limitations on professional activities.¹ The derivative effects of the need to make consequential decisions in unrelated fields entail social and economic impacts in addition to the outcome for public health. These factors have sparked many public discussions, but especially two questions that are closely related. The first involves the decision-making process or, in

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¹ The measures taken around the world vary widely, with intensity depending on the country. Examples of Covid-19 measures include: lockdowns (whether domicile, municipal, regional, national, or international), the closure of public spaces (parks for children or areas for community use), school and university shutdowns, restrictions on commercial activity (bars, shopping centers, cinemas, etc.) as well as professional and business activities in other sectors (limiting economic activity to industries deemed essential). For a general account about the world response to the Covid-19 from multiple angles, see the special section of the *Verfassungsblog on Matters Constitutional*: “Covid 19 and States of Emergency” (<https://verfassungsblog.de/states-of-emergency>).

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other words, who makes the decisions and what process is followed. Debate over the respective roles of politicians and experts in policymaking, however familiar, has been central during the debates over the responses to the Covid-19 crisis.² The second question concerns accountability for the results of the decision-making process. Clarification is needed to allocate responsibility for the response (or lack thereof) to the Covid-19 among the politicians and experts.³

This article explores these two interconnected interrogations from an institutional approach. It discusses institutional structures that favour productive relationships between politicians and experts and that, in turn, increase accountability for policy decisions that entail both political and scientific judgments. In this regard, the Covid-19 crisis exemplifies the challenging allocation of risk—in direct terms of human health—and the responsibility of those who allocate it. However, the allocation involves multiple factors which require different types of expertise, among which are sophisticated knowledge of economic and social sciences. Designing an institutional architecture for integrating and managing this multiple-risk scenario is anything but straightforward.

Still, in the end, the Covid-19 crisis relates to the classical debate over the democratic and technocratic state.⁴ At issue is ultimately who makes the decisions to address the threat and who is accountable for them. Elected representatives have the democratic legitimacy to make the decisions but they rely, to greater or lesser extent, on unelected experts. It is possible that the unprecedented complexity, at least in the current phase of a globalized world, of the Covid-19 crisis explains the resurgence of this debate, because there are so many factors to consider, from different fields of expertise and wide-ranging implications. The

² M. Flinders and G. Dimova, *Bringing in the experts: blame deflection and the Covid-19 crisis*, in *British and Irish Politics and Policy, Covid-19*, 2020, <https://blogs.lse.ac.uk/politicsandpolicy/bringing-in-the-experts-blame-deflection-and-the-covid-19-crisis/>. For a deep approach, beyond the Covid-19 crisis, about the interrelationship between the administrative state, agencies, politics, and experts, see A. Vermeule, *The Constitution of Risk*, New York, 2014, pp. 163-186.

³ M. Flinders, *Coronavirus blame games – who really benefits?*, in *The Conversation*, 2020, <https://theconversation.com/coronavirus-blame-games-who-really-benefits-135470>.

⁴ M. Shapiro, *Who Guards the Guardians. Judicial Control of Administration*, Athens GA, 1988, pp. 58-62.

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social welfare state and the European institutional architecture that was erected between the 1950s 1970s emphasised the role of politicians and politics, whereas the regulatory state, which led to increasing reliance on administrative agencies starting in the 1980s, delegated authority to unelected experts.⁵ The Covid-19 crisis offers an opportunity to compare these two different institutional approaches and analyse their effectiveness.

The article focuses on the debate within the European Union institutional architecture. The European Union itself as a supranational organization and its Member States represents since the Second World War an interesting laboratory for the study of both the social and regulatory state models.⁶ The first part of the article presents the regulatory EU framework for risk management constructed over decades. This framework has been the product of common agreement within the EU institutions and its Member States, and, at the end, this consensual approach has been determinative of the design of the institutions in charge of managing risk.

The second part of the article then examines the EU institutional architecture that developed within the EU common risk regulatory framework. I will describe the evolution of the regulatory state model in this context, that is, the decisions by the EU to opt for a “hard” or “soft” regulatory state depending on the area of risk. The EU combines the social and regulatory models in the sense that one or the other or both are adopted depending on the complexity and kind of choices to be made. The EU institutional architecture thus represents a rich mixture between the two models. I will argue that, in the area of risk to human health, the EU institutional architecture afforded a suitable response to the Covid-19 crisis.

The third and final part of the article analyses the Spanish response to the Covid-19 crisis. Spain is taken as a case study for

⁵ G. Majone, *The Rise of statutory regulation in Europe*, in G. Majone (ed.), *Regulating Europe*, London, 1996, pp. 49-59.

⁶ P. Magnette, *The Politics of Regulation in the European Union*, in D. Geradin, R. Muñoz, N. Petit (eds.), *Regulation through Agencies in the EU. A New Paradigm of European Governance*, Cheltenham and Northampton, 2005, pp. 3-23; T. Christensen, P. Laegrid, *Agencification and regulatory reforms*, in T. Christensen, P. Laegrid (eds.), *Autonomy and Regulation. Coping with Agencies in the Modern State*, Cheltenham and Northampton, 2006, pp. 11-12.

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multiple reasons. First, as an EU Member State it is embedded in the larger framework and is responsive to the same trends, including the EU common risk regulatory framework. Secondly, pushed by the EU, Spain has been implementing the regulatory state model, not without difficulties or internal resistance.⁷ A third important factor reason for focusing on Spain is the high toll of the Covid-19 crisis in Spain, both in terms of fatalities and infections, which forced the public authorities to take quick action along with Italy. I seek to show whether Spain’s response followed the EU common risk regulatory framework—through its derivative institutions—or, to the contrary, whether it chose a different path.

2. *The EU regulatory framework for risk management*

The paper adopts the terms of the current international agreement on risk analysis which divides the analysis into three stages: risk assessment, risk management and risk communication.⁸ This approach, which emerged in the 1980s, differentiated the role of experts from that of decision-makers (politicians) and especially sought to clarify what each brought to the policymaking process. This approach begins by recognizing the need for both expertise and political legitimacy in policymaking and seeks to distinguish their roles. The distinction is that experts are to be in charge of risk assessment—identifying and weighting the risk—while the decisionmakers are to define and implement the risk management measures necessary, taking into account the expertise with discretion to work in considerations for other factors or values.⁹ The model does not ignore the difficulty of

⁷ J. Solanes Mullor, *Administraciones independientes y Estado regulador. El impacto de la Unión europea en el Derecho Público español*, Madrid, 2016, pp. 179-305.

⁸ The distinction was elaborated for the first time in 1983 by the US National Research Council (NRC): National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, Washington, DC, 1983. This study and other publications of the NRC has influenced the way that risk is managed by many US agencies.

⁹ A. Alemanno, *Science & EU Risk Regulation: The Role of Experts in Decision-Making and Judicial Review*, 2007, available at SSRN:

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making a clear separation, admitting that the line between assessment and management is often blurry,¹⁰ but it attempts to maintain the separation for the sake of establishing clear roles that, subsequently, make individualized accountability easier to assign.

The advantages of this model are therefore clear. Firstly, it combines expertise and politics in risk analysis, considering that both perspectives are necessary. Expertise is key in the first stage of identifying risk and gauging its magnitude. The political process is determinant in the second phase for it allows the integration of the initial scientific assessment with factors that are also relevant to the final decision (the management of risk). Economic and social implications of the risk can be integrated in the risk analysis stage by politicians who possess democratic legitimacy. Secondly, once a decision is taken and it is time to evaluate its results and consequences, the separation of assessment and management facilitates the allocation of responsibility for success and failure.

Both the social and the regulatory state models are receptive to this framework for risk analysis and management. However, because of their different foundations and institutional structures, they approach risk in fundamentally different ways. The social (or welfare) state developed in Europe during the 1950s and 70s puts emphasis on the political process for the sake of democratic accountability, which reinforces the role of public intervention.¹¹ The characteristics of the social state are a strong regulatory presence in the economy and markets through state-owned enterprises along with the typical European continental bureaucracy—a professionalized hierarchical administration led by ministers appointed by elected governments and parliaments.¹² The regulatory state model, in contrast, relies much more on experts. The foundations of the regulatory state date back to the New Deal policies of the 1920s and 1930s in the United States and the 1980s in continental Europe. The emphasis on expertise puts the

<https://ssrn.com/abstract=1007401> or <http://dx.doi.org/102139/ssrn.1007401>), at p. 7.

¹⁰ National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society*, Washington, DC, 1996.

¹¹ G. Majone, *The Rise of statutory regulation in Europe*, cit., pp. 54-55.

¹² G. Majone, *Regulation and its modes*, in G. Majone (ed.), *Regulating Europe*, London, 1996, p. 11.

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private market in the centre and pushes democratic accountability and the political process to the periphery.¹³ The regulatory state favours largely independent agencies as the institutions for managing and regulating the private sector.¹⁴ The agency is thus relatively insulated from political institutions, affording greater independence for managers whose staff is selected on the basis of expertise on the field.¹⁵ The regulatory state thus represents a significant departure from the model of hierarchical public administration headed by an elected representatives. Instead it prefers agencies that perform less intrusive, more expertise based professional intervention in the private sphere.¹⁶

The risk analysis framework is interiorized differently depending on the state model. The characteristics of the social state limit the direct influence of experts on the decision-making process: experts play a secondary role because what ultimately matters is democratic accountability. When they are taken into account, they advise in consultative roles or within democratic institutions (as advisers to parliaments, governments or the public bureaucracy). This is not to say that experts are not integrated into the social state, but it remains true that the social state does not incorporate institutions like agencies that protect and isolate expertise. In contrast, the regulatory state does and, therefore, the separation between risk assessment and risk management is easier. The clearer separation between these two stages, made possible by agencies, makes the risk analysis framework easier to adopt in the regulatory state.

Ultimately, the relationship between politics and expertise is a question of equilibrium and degree. The social state tends to favour the political process and democratic accountability while the regulatory state shifts the emphasis to expertise and other notions of

¹³ G. Majone, *Theories of regulation*, in G. Majone (ed.), *Regulating Europe*, London, 1996, p. 28.

¹⁴ J. Solanes Mullor, *Administraciones independientes y Estado regulador*, cit., pp. 88-95.

¹⁵ M. Groenleer, *The Autonomy of European Union Agencies. A Comparative Study of Institutional Development*, Delft, 2009, pp. 125-128.

¹⁶ C. Pollit, K. Bathgate, J. Caulfield, A. Smullen, C. Talbot, *Agency Fever? Analysis of an International Policy Fashion*, in *Journal of Comparative Policy Analysis: Research and Practice*, n° 3(3), 2001, pp. 276-279.

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accountability, particularly procedural and transparency norms.¹⁷ Yet the regulatory state also has several manifestations, which leave more or less room to politics or experts. Some agencies may be powerful, able to make decisions that integrate assessment and management risk under expert control, while others may only consultative in nature, in which case political institutions are the primary actors and agencies and experts play more of a consultant role. Agencies vary in terms of the power they wield but always, whether decision-makers or consultants, isolate expertise from politics. This difference is key to understanding how each state model allocates the responsibility for risk analysis. The social model will tend to give power in both the assessment and management stages to politicians—maybe with experts in the hallways—while the regulatory model tends to put faith in experts at both the assessment and management stages, to greater or lesser degree depending on the powers granted to specific agency. In other words, the modulation of separation between the stages of risk analysis and the role of politics and expertise depends on the state model and its institutional architecture.

The EU risk regulatory framework has been assimilating the international risk analysis model for years.¹⁸ Its path, however, has been influenced by evolution in popularity of state models. At the very beginning, prior the explosion of the regulatory model in the 1980s, the EU institutional structure reflected that of its Member States where agencies were scarce. Its political institutions—the European Parliament and Commission—were the determinant in risk regulation. As the social state was predominant in Europe, the EU also based it on the political process and democratic accountability. The integration of expertise in decision-making was slow. The initial manifestations of the shift occurred towards the end of the 1980s and the beginning of the 1990s in judgments handed down by the Court of Justice of the European Union in the field of the internal market and free movement of goods.¹⁹

¹⁷ G. Majone, *Regulatory legitimacy*, in G. Majone (ed.), *Regulating Europe*, London, 1996, pp. 291-296.

¹⁸ A. Alemanno, *Science & EU Risk Regulation*, cit., pp. 2-5.

¹⁹ See the following seminal cases: Judgment of 12 March 1987, *Beer Purity case* (*Commission v. Germany*), C-178/84, EU:C:1987:126; Judgment of 13 December 1990, *Bellon*, C-42/90, EU:C:1990:475; Judgment of 4 June 1992, *Debus*, C-13/91 and 113/91, Case C-13/91 and C-113/91, EU:C:1992:247.

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Throughout the 1990s, expert risk analysis gained normative strength in EU treaties.²⁰ The integration of expertise at the EU level was accompanied by a rapid creation of agencies both at the EU and national levels. Indeed, during the 1990s and 2000s, agencies burst continental Europe, making the regulatory state reality.²¹ Giandomenico Majone is one scholar who has demonstrated how their adoption was influenced by the experience of the New Deal in the United States.²²

In this context, the risk regulatory framework has shifted in Europe from a political model to one more oriented towards expertise. This shift involves two important factors. First, it parallels a paradigm change in European countries, notwithstanding significant variations in intensity and degree, from social state to regulatory state models.²³ Second, this change has occurred at both the EU and national levels. In the 1990s and 2000s, the EU's turn to agencies as a new form of governance means EU agencies are now a fixed part of the EU institutional landscape.²⁴ EU member States, at the same time, also created national agencies which are now common in several sectors.²⁵ The interconnected spread of agencies at the EU and national levels together with the regulatory state model over the past three decades is an important phenomenon since the EU has not only has created EU agencies for internal operations, but has also encouraged legislation to

²⁰ See A. Alemanno, *Science & EU Risk Regulation*, cit., pp. 2-5.

²¹ D. Geradin, N. Petit, *The Development of Agencies at EU and National Levels: Conceptual Analysis and Proposals of Reform*, *Jean Monnet Working Paper 01/04*, New York University School of Law (2004), pp. 37-38.

²² G. Majone, *The Rise of Statutory Regulation in Europe*, cit., pp. 49-54.

²³ F. Gilardi, *Policy credibility and delegation to independent regulatory agencies: a comparative empirical analysis*, in *Journal of European Public Policy*, n° 9(6), 2002, p. 873; D. Coen, M. Thatcher, *The New Governance of Markets and Non-Majoritarian Regulators*, in *Governance: An International Journal of Policy Administration and Institutions*, n° 18(3), 2005, p. 330; D. Coen, M. Thatcher, *Network Governance and Multi-level Delegation: European Networks of Regulatory Agencies*, in *International Public Policy*, n° 28(1), 2008, p. 49.

²⁴ For a map of the current EU agencies, see the official website of the EU: https://europa.eu/european-union/about-eu/agencies_en.

²⁵ D. Geradin, N. Petit, *op. cit.*, pp. 8-10; M. Thatcher, *The creation of European regulatory agencies and its limits: a comparative analysis of European delegation*, in *Journal of European Public Policy*, n° 18(6), 2011, p. 798.

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create national agencies for risk management and regulation.²⁶ As a result, the EU and its Member States currently possess a common EU risk regulatory framework.

3. The varying degrees of the regulatory state in the EU

3.1. A “hard” regulatory state: the purer economic areas

The institutional architecture of the regulatory state, as mentioned above, is not uniform across all jurisdictions and subject areas. The common EU risk regulatory framework is articulated through different institutional approaches in which the balance struck between experts and politicians varies. I call “hard” the regulatory state model with strong agencies (that possess decision-making power) and “soft” the regulatory state model with powerless agencies (that are only consultative in nature). The common EU risk regulatory framework is maintained in both variations but the equilibrium between expertise and politics shifts.

In the “hard” regulatory state, agencies are the central locus of the public action. In certain sectors, agencies are in charge of policymaking and, therefore, risk analysis as well. In these areas, political institutions are secondary. Examples of these sectors are monetary policy and financial regulation—central banks, securities and exchange agencies—and the energy, telecommunication, and transportation sectors. In these sectors the theory of the regulatory state reaches its greatest expression because of the combination of several factors. The first determinant is the high trust in our societies in the private initiative and private market. As the economic activity in these areas is greatly privatized, the functions of the state are reduced to managing externalities and the guarding against market malfunction (ensuring minimal conditions for open competition in markets and protecting consumer rights).²⁷ Second, this “corrective” function is

²⁶ M. Thatcher, *Regulation after delegation: independent regulatory agencies in Europe*, in *Journal of European Public Policy*, n° 9(6), 2002, pp. 955-956; J. Solanes Mullor, *Institutional Balance, EU and National Agencification Processes: The Need for Dialogue*, in *Revista Española de Derecho Europeo*, n° 68, 2018, pp. 86-88.

²⁷ G. Majone, *Theories of regulation*, cit., pp. 28-29.

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conceived as highly technical, requiring above all expert knowledge of economic science. The regulation of markets conceived as avoiding malfunction is seen as politically neutral, the idea being that everybody gains from healthy markets (Pareto efficiency) so there is no redistribution of wealth that would require democratic legitimation.²⁸ Third, despite the determinacy of the economic sciences, other kinds of expertise are needed depending on the field—for instance, engineering in the energy and telecommunications sectors—so expertise is generally prized over political legitimacy.²⁹

The regulatory model’s attraction to empowered agencies as key institutions responds to these characteristics. Agencies are able to plan and implement long-term projects—without jeopardizing credibility—because of their immunity to electoral cycles.³⁰ The leadership of political institutions revolves with elections while the private actors operating in these sectors demand stability, or at least steadiness, in order to take better-informed decisions.³¹ Moreover, the institutional configuration of an agency protects expertise and ensures professional administration.³² The managers of the agencies may be nominated by

²⁸ The private market is the optimal organizer of the resources and public authorities only oversee its optimal functioning. The regulatory state, “correcting” the market, does not make redistribution of wealth policies, typical of the social (or welfare) state, such as the progressive tax measures. Thus, democratic legitimacy is less needed in the regulatory state because the “correcting” function does not imply redistribution and, therefore, there are no losers in the game. See G. Majone, *Regulatory legitimacy*, cit., pp. 294-296.

²⁹ In any case, the defenders of the regulatory state will call for the “depoliticization” of economic decisions and with this expression they understand that in these areas economic science is crucial. See G. Majone, *Europe’s ‘Democratic Deficit’: the Question of Standards*, in *European Law Journal*, n° 4(1), 1998, p. 28.

³⁰ G. Majone, *Nonmajoritarian Institutions and the Limits of Democratic Governance*. A Political Transaction-Cost Approach, in *Journal of Institutional and Theoretical Economics*, n° 157(1), 2001, pp. 61-63.

³¹ M. Thatcher, *Delegation to Independent Regulatory Agencies: Pressures, Functions and Contextual Mediation*, in *West European Politics*, n° 25(1), 2002, pp. 130-131; A. Wonka, B. Rittberger, *Credibility, Complexity and Uncertainty: Explaining the Institutional Independence of 29 EU Agencies*, in *West European Politics*, n° 33(4), 2010, pp. 734-736.

³² D. Levi-Faur, *Regulatory networks and regulatory agencification: towards a Single European Regulatory Space*, in *Journal of European Public Policy*, n° 18(6), 2011, pp. 811-812.

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political institutions, but legislation often requires that the nominees possess technical qualifications and previous experience in the field of action of the agency, and sometimes secures them long-term tenure.³³ The agency staff is also hired based on their expertise in the field.³⁴ In the “hard” regulatory state context, experts are protected by the configuration of the agency that insulates it from political influence. Finally, agencies in this context enjoy strong powers, sometimes all three powers typical of states themselves.³⁵ They have normative power, as expressed by the rules, regulations, and standards they determine; display adjudicative power when imposing sanctions or other administrative acts enforcing the norms; and perform a quasi-judicial role of arbitration when mediating controversies between private market agents.

This focus on agencies is visible at both the EU and the national level. In the field of monetary policy and financial regulation, the European Central Bank (ECB) could be considered the strongest EU agency of all, as its independence and powers are directly established by treaty.³⁶ However, other EU agencies have been recently created in the field of financial regulation.³⁷ At the national level, national central banks have also been pivotal, even in Member States in the Eurozone.³⁸ The role of national securities and exchange agencies is also

³³ M. Groenleer, *op. cit.*, pp. 122-124.

³⁴ M. Groenleer, *op. cit.*, pp. 125-128.

³⁵ R. Dehousse, *Misfits: EU Law and the Transformation of European Governance*, *Jean Monnet Working Paper 2/02*, New York University School of Law (2002), pp. 2-3; D.R. Kelemen, *The Politics of ‘Eurocratic’ Structure and the New European Agencies*, in *West European Politics*, n° 25(4), 2002, p. 94.

³⁶ The ECB regulation is found in a triad of EU treaties: Art. 13 of the Treaty on European Union (TEU), Art. 282-284 of the Treaty of Functioning of the European Union (TFEU) and Protocol n° 4 on the Statute of the European Central System of Central Banks and the European Central Bank.

³⁷ See the European Bank Authority (EBA) and the European Securities and Markets Authority (ESMA).

³⁸ National Central Banks of countries which belong to the Eurozone are now integrated in the so-called European System of Central Banks (ESCB) and perform important supervisory duties under the leadership of the ECB. See J. Solanes Mullor, *What Goes UP Must Go UP: Raising Judicial Scrutiny over the European Central Bank Through Judicial Dialogue*, in M. Below (ed.), *Judicial Dialogue*, The Hague and Chicago, 2019, pp. 155-162.

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significant.³⁹ In the energy and telecommunications sectors, meanwhile, the EU imposed on Member States the obligation to create and articulate powerful national agencies for these markets, particularly to ensure competition and safety.⁴⁰ Currently, the EU continues to require national agencies in energy and telecommunications fields but has also begun opening a path for the creation of EU agencies for them.⁴¹ In sum, as stated above, the interconnected spread of the regulatory state with its emphasis on agencies at the EU and national levels has been constant over the last three decades.

The spotlight on agencies in the “hard” regulatory state tips the scales of the balance between political process and technical expertise in favour of the latter. In these sectors, the policymaking role of political institutions is diminished. The political institutions often only appoint the managers of agencies and determine their general mandate through legislation. While political institutions are also ultimately responsible for the proper functioning and accountability of agencies, the day-to-day regulation of the sectors in question is independently carried out by the agency. This has significant implications for the common EU regulatory risk framework. The risk analysis in all these sectors is divided into the different stages of risk assessment, management and communication, but all are carried out within the agency and thus by experts.⁴² In this regard, most regulatory agencies have different teams

³⁹ At the national level, only financial regulators were common until the 90's. See M. Thatcher, *Regulation after delegation*, cit., p. 954.

⁴⁰ The obligation of articulating a national regulatory agency in the energy sector was first formulated in 2009 (Recital 34 and Article 35(4)(b)(ii) Directive 2009/72 and Recital 30 and Article 39(4)(b)(ii) Directive 2009/73). That obligation in the telecommunications sector was also imposed in 2009 (Articles 3 bis and Articles 6-12 Directive 2002/21, introduced by Directive 2009/140). Prior 2009, EU legislation left institutional freedom to Member States for organizing the energy and telecommunications regulators. Some States had powerless agencies or directly a hierarchical public administration managing the sectors. See J. Solanes Mullor, *Institutional Balance, EU and National Agencification Processes*, cit., pp. 97-98.

⁴¹ See the Agency for the Cooperation of Energy Regulators (ACER), created by Regulation (EC) No 713/2009) and the Agency for Support for BEREC (BEREC Office), created by Regulation (EU) No 2018/1971.

⁴² See supra note 8.

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or sections for the different stages of risk analysis.⁴³ Political institutions, in areas where the “hard” regulatory state model has been adopted, delegate risk analysis to experts (agencies). For that reason, the agency may be held accountable for mistakes in any of the stages of risk analysis.

Undoubtedly, the “hard” regulatory state has been subject to criticism. On the one hand, defenders of the regulatory state themselves worry about the “capture” of agencies by private agents in the market,⁴⁴ the cost and inefficiency of regulation⁴⁵ and the dispersion or lack of inter-agency coordination.⁴⁶ Particularly in countries where independent agencies have not traditionally been part of the political and legal culture, they face complicated obstacles.⁴⁷ Notwithstanding, the most damning criticism comes from outside the camp of defenders of the regulatory state who denounce the democratic deficit that results from the diminished role of political institutions. The critique especially centres on one of the key arguments for creating agencies: the alleged neutrality of agency activity (and the corollary, exclusive reliance on expertise for decision-making) that is based on the predominant assertion that there are no trade-offs in the economic management of the areas of the “hard” regulatory state. In other words, risk analysis should not be considered neutral for value judgments, especially in the management stage, will always be made.⁴⁸ For this reason, the “hard”

⁴³ *Ibid.* See, for a typical division inside of an agency, the “analysis and research” group of central banks, in charge of the risk assessment and the “managing board” of the central bank in charge of taking decisions (risk management).

⁴⁴ G.J. Stigler, *The Theory of economic regulation*, in *Bell Journal of Economics and Management Science*, n° 1(2), 1971, pp. 3-21.

⁴⁵ C.R. Sunstein, *Free Markets and Social Justice*, New York, 1997, pp. 322-326.

⁴⁶ C.R. Sunstein, *After the Rights Revolution*, Cambridge, London, 1990, pp. 93-94.

⁴⁷ J. Solanes Mullor, *Administraciones independientes y Estado regulador*, cit., pp. 317-320.

⁴⁸ A. Follesdal, S. Hix, *Why There is a Democratic Deficit in the EU: a Response to Majone and Moravcsik*, in *Journal of Common Market Studies*, n° 44(3), 2006, pp. 542-544; M. Everson, E. Vos, *European Risk Governance in a Global Context*, in E. Vos (ed.), *European Risk Governance. Its Science, its Inclusiveness and its Effectiveness. Connex Report Series*, n° 6, 2008, pp. 10-16; S. De Somer, *International and European Impulse with regard the Creation of Autonomous Public Bodies: an Emerging Trend*, in *UCL Journal of Law and Jurisprudence*, n° 3(1), 2014, pp. 85-86.

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regulatory state is confined to fields where there is sufficient consensus that the impact and scope of value judgments are minimal.

3.2. A “soft” regulatory state: risk to human health

There exist, however, several other fields of risk in which the EU risk regulatory framework has adopted a different institutional architecture in which agencies are not the protagonists. In several policy areas, the need for expertise and science is recognized in EU legislation but experts are not called upon to be the key players. The long list of policy fields in which the EU regulatory risk frameworks applies, that is, risk assessment and management are to be separated and political process and expert knowledge integrated, includes food safety, vehicle emission limits, water quality, consumer protection, worker safety and health, and the use of chemicals, biocides, genetically modified organisms (GMOs), pesticides and food additives.⁴⁹ In these fields, EU legislation is prolific and the EU and Members States share the competence for risk analysis.

The balance between politics and experts, however, shifts in comparison with the “hard” regulatory state. The “hard” regulatory model is adopted where confidence in economic science and the private market are highest. The belief in neutral public intervention in these areas is also strong; that is, it is thought that the agency interventions do not entail significant trade-offs. These beliefs are bolstered by confidence in the scientific expertise.⁵⁰ Other policy areas, however, are not as constrained to “private” markets and, therefore, the public interest and other value judgments are more visible across the policymaking process. Moreover, uncertainty over scientific expertise in these other fields also represents an important motive for cautious scepticism.⁵¹ For instance, in the area of food safety, EU legislation clearly separates risk assessment, which is assigned to experts (the European Food Safety Authority, or EFSA), from risk management (delegated to the Commission). Specifically the Commission managers

⁴⁹ A. Alemanno, *Science & EU Risk Regulation*, cit., p. 2.

⁵⁰ See supra note 28.

⁵¹ See Communication from the Commission on the precautionary principle, COM (2000) 1 final, 2 February 2000, p. 2.

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have the authority to incorporate into risk management measures “other factors legitimate to the matter under consideration”.⁵² In this and similar areas, the EU approach has been described as a system in which “scientific knowledge is authoritative, but not exclusively so”.⁵³

This approach has been determinant in the design of the institutional architecture for risk analysis. Before the 1980s, the social state model was predominant, and the EU and Member States political institutions were the key actors in the risk analysis framework in those areas. Particularly at the EU level, the decision-making procedures established by the EU treaties left the decision-making power in those fields in hands of EU political institutions, that is, the Council, the Parliament and the Commission. Experts were to advise the political institutions. This advisory role adopted different manifestations, which included external advisors in the form of reports provided by external consultants and institutionalized expertise in the form of in-house experts at the Commission or expert groups such as the Joint Research Centre (JRC) and the Scientific and Technical Options Assessment group in the Parliament (STOA).⁵⁴

The path towards the regulatory State in the 1990s led to improved integration of the expertise in those areas and several attempts to reinforce and harmonise the role of experts within the EU institutional framework.⁵⁵ Agencies, as the institutional choice most suited for the regulatory model, provided a new form of governance to explore at the EU level.⁵⁶ Instituting strong decision-making bodies headed by experts was not an option, however, because these sectors were less private-oriented, non-economic value judgments sometimes needed to be made and the reliability of the scientific research was still uncertain. In all those areas, then, EU agencies were created, but they

⁵² Article 7 and Article 19 of Regulation (EC) No 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed.

⁵³ G. Skogstad, *The WTO and Food Safety Regulatory Policy Innovation in the European Union*, in *Journal of Common Market Studies*, n° 39(3), 2001, p. 490.

⁵⁴ A. Alemanno, *Science & EU Risk Regulation*, cit., pp. 5-6.

⁵⁵ *Ibid.*

⁵⁶ See Communication from the Commission, *European Governance: a White Paper*, COM(2001) 428 final, 25 July 2001.

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were mostly given consultative roles without decision-making powers.⁵⁷ The regulatory state adopted a “soft” version in these areas because of the need to keep political processes at the centre of the risk analysis. Notwithstanding, the introduction of “soft” EU agencies changed the EU regulatory risk framework. Despite their consultative nature, they helped to uncouple expertise—provided by agencies—from politics—which was managed by political institutions, the Commission, the Parliament and Member States—and in so doing increased the visibility and transparency of the risk management process, especially in terms of the role of expertise and its accountability.

The “soft” regulatory state involves a compromise between democracy and technocracy. The EU political institutions were aware of this tension and only decided to implement the “hard” regulatory model with strong decision-making agencies and experts at the top in selected areas. In the other fields where value judgments and scientific uncertainty were more prevalent, even defenders of the regulatory model during the 1990s and 2000s, such as the EU Commission itself, favoured consultative rather than decision-making agencies.⁵⁸ The EU institutions chose to keep decision-making in the hands of political bodies in those areas but they nevertheless bolstered the role of expertise by cabining it off from the political organs. Although they were generally limited to advisory role, the creation of many new EU agencies in the 1990s and 2000s afforded these expert bodies greater

⁵⁷ Most of the agencies are only consultative in nature, such as the European Environment Agency (EEA) and the European Agency for Safety and Health Work (EU-OSHA). Some have limited adjudicative powers (capacity for granting authorizations in the field) such as the European Food Safety Authority (EFSA) or the European Medicines Agency (EMA). In short, the EU agencies in those public health fields have either no powers or limited adjudicative powers. See J. Solanes Mullor, *Administraciones independientes y Estado regulador*, cit., pp. 152-160.

⁵⁸ Communication from the Commission, *European Governance: a White Paper*, COM(2001) 428 final, 25 July 2001, pp. 27-28; Communication from the Commission on the European Governance: Better lawmaking, COM (2002) 275 final, 5 June 2002, p. 5; Communication from the Commission on the operating framework for the European Regulatory Agencies, COM (2002) 718 final, 11 December 2002, pp. 12-13; Communication from the Commission on the European agencies: the way forward, COM (2008) 135 final, 11 March 2008, p. 5.

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independence.⁵⁹ In this context, the balance between expertise and political legitimacy in the policymaking process was tipped in favour of political institutions, which drive the process and take the decisions, while consultative agencies provide needed expertise and, importantly, protect the integrity of experts by institutionally isolating them from undue political pressure.

The EU public health risk regulatory framework is a clear example of a “soft” regulatory state institutional design. Food safety, chemical regulation, environmental and water protection are all areas set up under the public health regulatory framework. Although all these areas take a similar institutional approach, I will limit myself to the risk analysis associated to public health regarding the prevention and control of cross-border human diseases before turning attention to the Spain case study. The prevention and control of cross-border human diseases is the most relevant and specific area of risk regulation for examining the response to the Covid-19 crisis. Indeed, European countries are primarily facing a cross-border epidemiologic crisis because of which the cross-border human diseases regulatory framework is being tested across the continent. Of course, the public health crisis encompasses multiple dimensions, such as the economic decline, but ultimately the driving factor remains the cross-border health threat.

Against this backdrop, it is important to remember that the EU adopted a “soft” regulatory state approach for interiorizing the risk analysis of cross-border human diseases. The institutional design is complex and its balance between politics and expertise in the field of human health risk analysis, has been shifting toward a more politically-oriented system.⁶⁰ Indeed, the institutional architecture comprises three key players: the European Centre for Disease Prevention (ECDC), the EU Commission and the Member States. This triad oversees or

⁵⁹ J. Trondal, L. Jeppesen, *Images of Agency Governance in the European Union*, in *West European Politics*, 31(3), 2008, p. 419.

⁶⁰ Currently, the institutional framework is established by 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 (Decision No 1082/2013/EU)

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carries out the risk analysis of cross-border human diseases yet only the ECDC is an expertise-based agency.⁶¹

The ECDC is in charge of the risk assessment, but no more: the Commission and Member States are in charge of the ensuing risk management phase.⁶² The ECDC has collected data on the Covid-19 crisis and assessed the risk through several reports.⁶³ The ECDC also coordinates a network for epidemiological surveillance, which complements the “national competent authorities”.⁶⁴ This network is to share information and comparable data. The conjecture is that having an EU agency coordinate the national surveillance apparatuses will have the effect of giving experts a leading role. However, no EU-level institutional requirements from the EU level determine the characteristics of those “national competent authorities” and, therefore, Member States are able to tap a political institution or a national agency to participate in the network.⁶⁵ In that regard, the ECDC is asked to coordinate a very diverse galaxy of national bodies, most of which are not agencies.

Setting aside the role of the ECDC, Member States are called to take the decisions and, at the end, they manage the cross-border human diseases risk.⁶⁶ The Commission has a coordination role, but the Covid-19 crisis has shown that its centrality has not translated into power.⁶⁷ In

⁶¹ The ECDC was created by Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control. The Management Board shall be composed of one member designated by each Member State, two members by the European Parliament and three members appointed by the Commission (Article 14.1). The members of the Board “shall be appointed in such a way as to secure the highest standards of competence and a broad range of relevant expertise” (Article 14.2).

⁶² The ECDC duties on risk assessment are laid down in Article 10 Decision No 1082/2013/EU. The Member States and the Commission roles in the managing stage are mainly regulated in Article 11 Decision No 1082/2013/EU.

⁶³ See the ECDC’s reports on risk assessment in: <https://www.ecdc.europa.eu/en/current-risk-assessment-novel-coronavirus-situation>.

⁶⁴ Article 6 Decision No 1082/2013/EU.

⁶⁵ *Ibid.* at Article 15.

⁶⁶ *Ibid.* at Article 11.

⁶⁷ See the role of the Commission explained by the own institution in: https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_307. It should be

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fact, most of the major decisions to manage the crisis have been purely national while the Commission action has been timid.⁶⁸ Along with the Commission, the so-called Health Security Committee seeks to ensure a coordinated response from all Member States to a cross-border human disease threat.⁶⁹ In short, even if coordinated, the management of the risk is left to Member States without any requirement at the EU level that the national authorities consist of independent agencies. The ECDC, charged with the assessment risk stage, is the only actor that is imperatively an agency. The institutional design for the cross-border human disease risk regulatory framework in the European Union thus reflects a form of the “soft” regulatory state combining expertise at the assessment stage—through the ECDC and its network—and political decision-making at the management stage—where Member States and the Commission comprise the decision-makers.

Beyond the debate over the effectiveness, soundness and timeliness of this triad system’s response to the Covid-19 crisis, the institutional framework has functioned as expected with regards the role of each actor.⁷⁰ The ECDC has issued several technical reports for assessing the risk of the Covid-19, the Commission has made efforts to coordinate and assist Member States and the latter have effectively taken the decisions on the ground. There is room to discuss the proper

highlighted that the Commission shall be assisted by a committee on serious cross-border threats to health. This is a scientific committee in line of Article 3(2) Regulation (EU) No 182/2011. See Article 18 Decision No 1082/2013/EU.

⁶⁸ I. Toygür, *The EU, coronavirus and crisis management: is ‘solidarity’ real or just a prop?*, Expert Comment 8/2020, Royal Institute Elcano: http://www.realinstitutoelcano.org/wps/portal/rielcano_en/contenido?WCM_GLOBAL_CONTEXT=/elcano/elcano_in/zonas_in/commentary-toygur-eu-coronavirus-and-crisis-management-is-solidarity-real-or-just-a-prop.

⁶⁹ The Health Security Committee (HSC) is composed of representatives of all Member States and chaired by a representative of the Commission. See Article 17 Decision No 1082/2013/EU.

⁷⁰ See, about the EU regulatory framework and its response to the Covid-19 crisis, A. Renda and R. Castro, *Towards Stronger EU Governance of Health Threats after the Covid-19 Pandemic*, in *European Journal of Risk Regulation*, n° 11(2), 2020, pp. 273-282; A. Paces and M. Weimer, *From Diversity to Coordination: A European Approach to Covid-19*, in *European Journal of Risk Regulation*, n° 11(2), 2020, pp. 283-296; A. Alemanno, *The European Response to Covid-19: From Regulatory Emulation to Regulatory Coordination?*, in *European Journal of Risk Regulation*, n° 11(2), 2020, pp. 307-316.

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role for each actor—whether, for example, the Commission should be more active in the area of coordination. It is also worth asking if Member States should be act less unilaterally in the face of a cross-border threat, yet it remains the fact that expertise and politics in the EU institutional framework have been acting separately. Another necessary debate involves the visibility of the ECDC, which remains mostly unknown to the European public although it has been providing expertise to EU institutions and Member States through the European institutional framework for requesting action from this agency.

4. Spain in the context of the EU health risk management framework

4.1. The Spanish institutional architecture for facing the Covid-19 crisis

The Spanish health human risk institutional architecture is not aligned with the EU risk regulatory framework. Its approach does not separate the three risk analysis stages and, especially, it does not properly integrate expertise in risk analysis. Considering the EU approach to public human health, one may have expected Spain to adopt a “soft” regulatory state in Spain;⁷¹ that is, a politically-tilted model that brings in expertise through consultative agencies. In other words, the EU stand in human diseases risk analysis encourages a system that leaves management to political authorities and risk assessment to experts through agencies. In the case of Spain, however, the management and assessment stages are blurred, and the role of experts is ambiguous.

Indeed, Spain has largely maintained a classical social state model approach to public human health risk analysis, where the only agency are exceptional minor cases at the autonomous community level that

⁷¹ Only in relation to food safety has Spain adopted a sort of “soft” regulatory state with the creation of the Spanish Agency for Food Safety and Nutrition (created by Law 11/2011, of 5 July). This is a consultative agency without decision-making powers.

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have small quasi-agencies.⁷² There are two parallel institutional frameworks in the Spanish public health system. On the one hand is a set of institutions established for the “ordinary” management of the public health system.⁷³ On the other exists a specific institutional framework and procedures established for human disease crises, that is, for the assessment and management of public human health threats.⁷⁴ Both institutional systems respond to the logic assigning decision-making to political authorities and relegating experts to a consultative role—yet without the protection from political influence that agencies provide.

The first institutional framework—the “ordinary” management of public health—mostly relies on the autonomous communities for the operation of their respective public health systems.⁷⁵ Most of these sub-state entities have opted for a typical bureaucratic public administration, with political health departments in charge of the territorial public health systems. Only Catalonia and Castile and León have set up quasi-agencies in the public health area.⁷⁶ When taking coordinated decisions in public health at the national level is needed, the Ministry of Health takes the lead.⁷⁷ Here again, a political department, this time one responding to the Spanish executive, is the key actor. The Ministry of Health, in taking these coordinated decisions, is assisted by the so-called Interterritorial Council of Health,

⁷² Specifically, only two autonomous communities have set up a quasi-agency: Catalonia (Agency of Public Health of Catalonia) and Castile and León (Agency for the Protection of Health and Food Safety). These bodies have their own legal personality, but lack all the characteristics of an agency, especially as the board is composed by members of the public administration and the directors can be removed at will by the political authorities.

⁷³ See Law 16/2003, of 28 May, on cohesion and quality of the National Health System (Law 16/2003). The law articulates the basic system for the entire territory and, accordingly, the autonomous communities organize their own public health systems.

⁷⁴ See Law 33/2011, of 4 October, on Public Health.

⁷⁵ The State has the competence for establishing the “basis and general coordination of health” (Article 149.1.16 of the Spanish Constitution). Thus, the State approves the minimum legislative corpus and then the autonomous communities, in their respective Statutes of Autonomy and their own legislation, develop this minimum and organize and operate their own public health systems.

⁷⁶ See *supra* note 72.

⁷⁷ Article 65 and 65 bis. Law 16/2003.

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which integrates the Minister of Health as a President and all the heads of the health departments of the autonomous community governments.⁷⁸ The “ordinary” management, therefore, rests in hands of political institutions, both at the central and autonomous community levels. That does not imply that experts have no role inside these political structures. Indeed, these political departments include technical staff.⁷⁹ Moreover, the Interterritorial Council of Health has the power to create commissions and groups to provide expertise for the decision-making process.⁸⁰ However, the separation between the risk management phases is difficult to make out clearly and the experts are left in the shadows.

For our analysis of the response to the Covid-19 crisis, the institutional arrangement for addressing human public health threats was identified as the most relevant framework. In this area we encounter in Spain a timid approximation to the “soft” regulatory state in line with the EU’s stance, but despite those gestures, the country is still following a different path. This institutional design sets up an administrative body, the Health Alert and Emergency Co-ordination Centre (CCAES), which is charged with assessing the public health threat.⁸¹ Once a threat has been identified, the CCAES carries out the risk assessment with the needed experts and assistance from the autonomous communities.⁸² In that regard, the risk assessment is performed by a network coordinated by the CCAES that integrates more experts and the autonomous communities. The CCAES also represents the “national competent authority” integrated in the network for the epidemiological surveillance headed by the ECDC.⁸³ Afterwards, the CCAES communicates the risk assessment report and proposed measures to the Ministry of Health and the Commission of

⁷⁸ Articles 69 – 75 Law 16/2003.

⁷⁹ The expertise is provided through the articulation of public examinations - which incorporate the need to prove technical knowledge in the health area- for the selection of the staff of the health departments.

⁸⁰ Article 74 Law 16/2003.

⁸¹ See Article 4 Order SCO/564/2004, of 27 February, which creates the coordination system of alerts and emergencies in the areas of health and consumption.

⁸² Sistema de Alerta Precoz y Respuesta Rápida (SIAPR), approved by the Commission of Public Health (6 February 2013) and the Interterritorial Council of Health (21 March 2013), p. 7 and 10.

⁸³ See Order SCO/3870/2006, of 15 December.

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Public Health of the Interterritorial Council of Health, which will be in charge of managing the risk and, therefore, take the decisions.⁸⁴ The institutional framework thus involves co-governance between the central government, which is predominant, and the autonomous communities.

The CCAES, however, is not an agency. Its status is precarious. Its founding regulation does not have the rank of legislation; that is, it was created and regulated by an “order” from the Ministry of Health. This is significant, for normally agencies are articulated by legislation; that is, their legitimacy is secured by a decision of the parliament. Moreover, within the structure of the Ministry of Health, the CCAES represents a “unit” located within the Cabinet of the Minister.⁸⁵ Presently, the CCAES is ascribed and therefore responds to the General Directorate of Public Health.⁸⁶ Lastly, the CCAES has one director, four sectorial chiefs and only four technical experts.⁸⁷ The size of the team is thus reduced with only four technicians supporting five managerial staff.

The shortfalls of the CCAES are clear. First, it lacks independence or autonomy. The CCAES is not institutionally shielded as agencies are; that is, it directly depends on the political appointments at the Ministry of Health. The position of the director and the staff are unprotected by any measure typical of agencies. The lack of secure tenure of the director and the prohibition of removing the director from the office without good cause are particularly concerning. The director position of the CCAES is conceived as a political appointment which can be assigned at political will. Secondly, even its existence as a body is in jeopardy because it can be eliminated by a mere “order” of the Minister. Indeed, the CCAES lacks the protection of law enacted by the parliament, so the executive has the authority to eliminate it or alter its

⁸⁴ Sistema de Alerta Precoz y Respuesta Rápida (SIAPR), approved by the Commission of Public Health (6 February 2013) and the Interterritorial Council of Health (21 March 2013), p. 8 and 10.

⁸⁵ See Article 4.2 Order SCO/564/2004, of 27 February, which creates the coordination system of alerts and emergencies in the areas of health and consumption.

⁸⁶ Article 7.7 Royal Decree 1047/2018, of 24 August, on the structure of the Ministry of Health, Consumption and Social Welfare.

⁸⁷ In accordance with the data provided by the document which describes the staff of the Ministry of Health of 4 June 2020, p. 21 (https://transparencia.gob.es/transparencia/transparencia_Home/index/PublicidadActiva/OrganizacionYEmpleo/Relaciones-Puestos-Trabajo/RPT-MSND.html).

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status. Third and finally, while the CCAES has some technical staff, it seems clearly underfunded. Of course, the CCAES can call on other expert entities and bodies which are designed to support its task, for instance the National Centre of Epidemiology of the Institute of Health Carlos III, but it clearly lacks a robust staff of its own.⁸⁸

In short, the Spanish institutional architecture described above represents a dated approach to public health risk analysis. In “ordinary” scenarios, risk management is completely delegated to political authorities who consult in-house or contracted experts in their discretion, whereas in case of public health threats, the institutional crisis framework introduces the CCAES. The CCAES represents a key actor for expertise in the assessment risk stage, but it lacks the institutional parameter of an agency. In theory, the CCAES assumes leadership of risk assessment in the system and the political bodies—the central and autonomous community authorities—represent the decision-makers. However, because the CCAES and its expertise is not protected, it is difficult to consider it an autonomous and independent body within the Ministry of Health. From an institutional point of view, the CCAES is an expert body, yet one that is an appendage of a political body and completely reliant on its will.

4.2. The management of the Covid-19 crisis

The Covid-19 crisis severely tested this politically-oriented institutional architecture. Spain has faced a severe health threat resulting in thousands of deaths and severe illness.⁸⁹ Beyond the sanitary emergency, Spain has also suffered an economic shock through the loss of jobs and business due to restrictions imposed by public

⁸⁸ For more information about the role and functions of the National Centre of Epidemiology of the Institute of Health Carlos III, see Articles 48-52 Law 16/2003.

⁸⁹ For all the official data of the Covid-19 pandemic in Spain, see the official website of the Ministry of Health: <https://www.mscbs.gob.es/en/profesionales/saludPublica/ccayes/alertasActual/nCoV-China/home.htm>.

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authorities to contain the virus.⁹⁰ The sanitary and economic crisis has also encompassed related challenges, such as education with the closing of schools and universities, or maintaining social relationships, with the prohibition of in-person meetings with family and friends. Spain has been forced, as have many countries, to apply drastic measures to manage the Covid-19 crisis. The Spanish human diseases risk framework has been under stress and its politically-oriented institutional architecture has hindered management of the Covid-19 crisis.

Indeed, the political orientation has actually received a boost during the crisis. The pivotal decision justifying all the measures taken—the constitutional umbrella that covers all the exceptional measures—was the ‘state of alarm’, as it is termed.⁹¹ This constitutional measure is decreed by the government for a period of fifteen days following which the parliament may authorize its extension.⁹² Thus, the political institutions are in charge of activating and extending this constitutional measure which has been used actively during the Covid-

⁹⁰ In the first trimester of 2020, the GDP shrank 5.2%. The loss of jobs was accused and in total approximately for and half millions of people lost their job or were affected in some way (with temporary layoffs or forced inactivity). See the Annual Report of the Spanish Central Bank of 2019, p. 23: https://www.bde.es/bde/en/secciones/informes/Publicaciones_an/Informe_anual/. In the second trimester of 2020, the GDP shrank 18,5%, the worst quarter-on-quarter contraction to date. See the reports of the National Institute of Statistics: https://www.ine.es/dyngs/INEbase/en/operacion.htm?c=Estadistica_C&cid=1254736164439&menu=ultiDatos&idp=1254735576581.

⁹¹ Article 116 of the Spanish Constitution. For a general approach about the multiple constitutional challenges that the state of alarm has generated in Spain, see G. Ruiz-Rico Ruiz, *Las dimensiones constitucionales de la crisis sanitaria en España. Dudas e incertidumbres presentes y futuras*, in *DPCE Online*, n° 43(2), 2020, pp. 1512-1519; V. Piergigli, *L'emergenza Covid-19 in Spagna e la dichiarazione dell'estado de alarma. Ripercussioni sul sistema istituzionale e sul regime dei diritti*, in *DPCE Online*, n° 43(2), 2020, pp. 1533-1563; D. Baldoni and S. Gherardi, *Due modelli costituzionali per governare l'emergenza. Italia e Spagna alla prova del Coronavirus*, in *DPCE Online*, n° 43(2), 2020, pp. 1591-1612.

⁹² The state of alarm is declared by the government by means of a decree for a maximum period of fifteen days. The Congress of Deputies shall be informed and must meet immediately for this purpose. Without their authorization the said period may not be extended.

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19 crisis.⁹³ There is no doubt that the activation of this clause should rest with political institutions. However, the state of alarm has exceptionally altered the human disease risk institutional framework. Indeed, under this constitutional measure, all the powers of the management of the crisis were assigned to the central government.⁹⁴ The co-governance of the risk analysis framework between the central government and the autonomous communities—with the Ministry of Health and the CCAES as key players on one side and the Interterritorial Council of Health on the other—shifted in favour of the centre. This balance was restored after the state of alarm was ended and management moved into a post-lockdown scenario.⁹⁵

In this context, the central government emerged as the key actor in managing the Covid-19 crisis. The CCAES, located in the Ministry of Health, has provided the expertise for the central government which has taken the decisions. However, confusion between the CCAES and the government—especially the Ministry of Health—has been constant. For one thing, the CCAES has actively communicated with the government regarding the Covid-19 situation and the measures taken. The CCAES and its director, however, have not been given their own communicational space. All the press conferences and official communications have been issued together with the central government authorities, especially the Minister of Health, and in the offices of the Ministry.⁹⁶ At the same time, the CCAES has been communicating all its information online through the Ministry of Health website, representing another area where it again lacks its own

⁹³ The Spanish government declared the state of alarm the 14 March 2020 for a period of fifteen days (Royal Decree 463/2020, of 14 March). Subsequently, the parliament has extended the state of alarm six times, finalizing the state of alarm the 21 of June 2020.

⁹⁴ Article 4 Royal Decree 463/2020, of 14 March.

⁹⁵ The finalization of the state of alarm implied the return to the institutional normality and, therefore, to the normal distribution of competences between the central and regional governments.

⁹⁶ All the official statement and press conferences are in the official website of the Ministry of Health: <https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov-China/videosPrensa.htm>.

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communication space.⁹⁷ At the same time, the proper function of the CCAES, risk assessment, has been blurred because it does not issue conventional risk assessment reports such as the ECDC.⁹⁸ Instead, the CCAES has relied on official statements, press releases and video conferences, always issued together with the central government, to communicate the risk assessment.

These factors have led to the confusion of the CCAES with the central government. The CCAES has not been able to assert its own profile or identity. Thus, the risk assessment and management phases of the crisis response have been confused. It was difficult to distinguish between the CCAES expertise on risk assessment and the central government’s management of the crisis. In the end, the CCAES and the central government shared all the same communicative spaces, whether videoconferences, press releases, official communications, and website. Expertise and politics were blurred, as was the line separating the assessment and the management stages of crisis response. The central government’s emphasis on expertise, however, has been constant. In that regard, as a way of legitimation, the central government has always stressed that its measures are based on the available expertise.⁹⁹ In that line, the presence of the CCAES or its director in most of the official communications has signalled the government’s reliance on expertise.

The confusion between the CCAES and the government, and ultimately between experts with politicians, has started a fight for expertise. And worse yet, experts have lost credibility during the Covid-19 crisis. The opposition parties criticized the government’s measures, including the way the CCAES was created, and called for basing

⁹⁷ See the website dedicated to the Covid-19 crisis, located at the Ministry of Health master website: <https://www.msbs.gob.es/en/profesionales/saludPublica/ccayes/alertasActual/nCoV-China/home.htm>.

⁹⁸ The CCAES has issued risk assessment report in various cases until 2019 (see: <https://www.msbs.gob.es/profesionales/saludPublica/ccayes/analisisituacion/infoSituacion.htm>). However, for the Covid-19, the CCAES has opted for official statement, press releases and videoconferences, but not for writing down a proper risk assessment report.

⁹⁹ See the official statement issued by the President of the Government Pedro Sánchez: https://www.lamoncloa.gob.es/presidente/actividades/Paginas/2020/09052020_fase1.aspx.

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decisions based on more expertise.¹⁰⁰ The opposition even requested the removal of the director of the CCAES, whom they associated it with having a role in the government’s management of the crisis.¹⁰¹ During the confusion, the government realized that limiting the CCAES to a role as an expertise provider was insufficient and announced the creation of a committee of experts.¹⁰² The role of this committee has not been made clear and whether it has ever been consulted in the management of the crisis or any governmental measure is unknown.¹⁰³ One member of the committee even publicly complained that he was not consulted before the crucial decision of terminating the lockdown.¹⁰⁴

Criticism of the government for taking decisions not based on expertise also came from the autonomous community governments. The sub-state entities were relegated in the management of the Covid-19 crisis leading some of them adopted a critical position against the central government.¹⁰⁵ What is more interesting is that the calls from the regional level for expertise centred on the lack of experts assisting the central government.¹⁰⁶ The CCAES seemed unable to legitimize the

¹⁰⁰ See https://www.antena3.com/noticias/espana/la-oposicion-critica-la-falta-de-claridad-del-plan-del-gobierno-para-la-desescalada-por-el-coronavirus_202004285ea89081ae15870001574536.html.

¹⁰¹ See <https://www.esdiario.com/447540172/Vox-rompe-un-tabu-y-pide-la-dimision-de-Fernando-Simon-por-no-dar-una.html>.

¹⁰² See the official statement of the Spanish Government: <https://www.lamoncloa.gob.es/presidente/actividades/Paginas/2020/210320comite.aspx>.

¹⁰³ Recently, the Spanish Government has recognized that this committee never existed outside the structure of the CCAES. See: <https://www.rtve.es/noticias/20200730/sanidad-reconoce-no-hubo-comite-expertos-para-desescalada-margen-del-equipo-fernando-simon/2034841.shtml>.

¹⁰⁴ See <https://www.publico.es/politica/miembro-del-comite-expertos-dice-gobierno-no-consulta-vuelta.html>.

¹⁰⁵ See, especially, the critiques from the Catalan regional Government: <https://www.ultimahora.es/noticias/nacional/2020/03/21/1150437/torra-internacionaliza-criticas-gobierno-por-covid-19.html>.

¹⁰⁶ See, from Catalonia, the critiques: <https://www.lavanguardia.com/politica/20200414/48501010791/budo-escriba-gobierno-govern-confinamiento-total-expertos.html>. In relation to the Autonomous Community of Madrid, the regional government contested the measures taken by the central government not allowing to advance to another phase of the deescalated lockdown based on the lack of technical expertise of those measures. See:

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government’s decisions, precisely because the CCAES was also conceptualized as part of the central government from the autonomous communities’ perspective. Some autonomous communities ended up contracting their own experts which bolstered the polarization of the debate among experts.¹⁰⁷ In the end, the spectacle of experts debating in the press was constant, creating a clear impression that expertise authority lacked at both central and regional levels. The impression that credible expertise leadership is lacking has led to demands from some Spanish experts for an independent investigation and hearings about the Spanish government’s management of the Covid-19 crisis.¹⁰⁸

The politically-oriented institutional architecture hinders the clarification between the analysis of the risk and the role of experts. The advantage of having politicians take the lead of risk management is clear, especially in the Covid-19 crisis, which entailed multiple risks and value judgments. There has been little criticism of the need to make political choices and value judgments. However, requests have clearly been made to integrate expertise into the overall management of the crisis or, to put it better, questions over the role of experts in the different phases of the crisis have become salient. The politically-oriented institutional architecture has not been useful in that regard. The CCAES does not constitute an agency and its experts are generally considered part of the government. The confusion between the CCAES and the government has affected the credibility of experts in the decision-making process. At the end, the weakness of the CCAES, the creation of dubious expert committees and the nomination of informal experts as advisors have all contributed to the confusion over the experts’ role in the Covid-19 crisis.

The “soft” regulatory state model, adopted at the EU level in the human health disease threat framework, may help in rethinking the Spanish model. The creation of a public health agency, one that possesses autonomy and independence and isolates expertise from

<https://www.lainformacion.com/espana/madrid/ayuso-madrid-desescalada-fase-politica-requisitos-informes-psoe-pp-coronavirus/6567780/>.

¹⁰⁷ For instance, the Catalan regional government nominated informal non-remunerated experts. See: https://cronicaglobal.lespanol.com/politica/oriol-mitja-asesor-cataluna_335469_102.html.

¹⁰⁸ See: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31713-X/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31713-X/fulltext).

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politics, seems a clear path to clarify the role of experts in crises such as the one posed by Covid-19. Indeed, voices in Spain have called for such an agency.¹⁰⁹ However, the immediate response of the central government has been creating a State Secretary, a political structure that is housed inside the Ministry of Health is only separated by one rank from the Minister.¹¹⁰ Meanwhile, the CCAES, despite the soundness of its expertise, has been superseded and its institutional features do not afford separation of its expertise from the government. The Covid-19 crisis in Spain has revealed deficiencies in the country’s risk analysis framework, especially in the separation between risk assessment and management, and the primary cause is deficient institutional design—the lack of an agency—that separates experts from the political bodies.

5. Conclusions

The Covid-19 crisis has been a challenge for all risk analysis institutional frameworks. The multiple risk scenario characteristic of pandemics constitutes a severe resistance test for any decision-making processes around the world. Governments are facing a health crisis with multiple derivative effects—economic, social, and cultural—for citizens. Clearly, a more consolidated institutional system could improve crisis response. More than ever, institutional studies are needed to analyze the performance of institutions and decision-makers during the Covid-19 crisis. The improvement of systems for governance with managing polyvalent crises such as Covid-19 is also an urgent need. This article provides an initial approximation to compare the EU and the Spanish perspectives.

¹⁰⁹ See: <https://elpais.com/sociedad/2020-05-16/los-17-sistemas-sanitarios-necesitan-un-mecanismo-que-los-unifique.html>. In that regard, there have been voices at the political level to create this agency. See: <http://isanidad.com/167073/psoe-y-ciudadanos-acuerdan-crear-una-agencia-nacional-de-salud-publica-una-peticion-inicial-del-pp/>.

¹¹⁰ See Royal Decree 722/2020, of 31 July. Before the Covid-19 crisis, the Ministry of Health lacked a Secretary of State, only had several general directorates without the superior rank of secretaries of state, such as the General Directorate of Public Health.

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Indeed, one of the key debates over the management of the pandemic has been the relationship between politics and expertise and, consequently, accountability for the decisions made. The EU approach represents an interesting proposal in this debate. On the one hand, the EU has adopted a consensual international model for risk analysis that separates risk assessment, risk management and risk communication. Experts are determinant and are to be integrated in all the framework, especially at the risk assessment stage. On the other hand, the EU has opted for two different versions of the regulatory state—the “hard” and “soft” models— depending on the area in question. First, the “hard” regulatory state has been chosen for areas, such as financial regulation, energy, or telecommunications, where powerful agencies are in charge of risk analysis. The “soft” regulatory state was chosen for areas, including most of the public health risk areas such as human diseases, in which consultative agencies provide expertise but political organs remain the decision-makers. The EU combines these two versions of the regulatory state depending on the nature of the activity in question, whether it concerns predominantly private-market or public interest values. The level of scientific certainty in the field is also a crucial factor in choosing between a more “hard” or “soft” regulatory state model.

In any case, the “soft” regulatory state model presents enormous advantages. It leaves the decision-making in the hands of politically legitimate authorities. When the scientific knowledge is ambiguous, multiple public interests are at issue and, ultimate, value judgments are necessary, democratic legitimacy is needed. However, expertise is integrated into each phase of the policymaking process through agencies. The institutional design of agencies protects experts and shields them from political institutions. In the case of human health threats, the EU institutional approach responds to the “soft” regulatory state model. Thus, it first separates the risks analysis stages by assigning the risk assessment to the ECDC and the management and communication to the Commission and Member States. Secondly, an agency—the ECDC—isolates and protects expertise. Throughout the Covid-19 crisis, all the actors have acted in accordance with their role.

The Spanish institutional architecture, however, presents clear shortfalls. The public health risk institutional architecture is politically-oriented and is out of alignment with the “soft” regulatory state model. In the case of human health threats, the system relies on political

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institutions—the central and autonomous community governments—and expertise is provided by an administrative body—the CCAES—which is not an agency. The system does separate risk assessment and risk management, but the experts lack autonomy and independence. The CCAES does not have any of the advantages of an agency, such as secure tenure for its director or the board, and this makes distinguishing the CCAES from the governmental action difficult. The Covid-19 crisis has vividly revealed these institutional shortfalls and put the role of expertise into an uncomfortable spotlight. The CCAES has been confused with the government, opening it to political crossfire that diminished its reputation and, in turn, the authority of its expertise in the decision-making process. In the end, the Covid-19 crisis exploded in a major conflict between experts in Spain—between the CCAES, *ad hoc* committees, informal experts nominated by governments and experts quarreling in the media—which has damaged the credibility of experts and, in the end, hindered measures taken to fight the pandemic.

The Spanish experience in managing the Covid-19 crisis reveals the shortfalls of its old-fashioned institutional design, which remains largely reflective of the social state model. The Spanish institutional system was not sufficiently prepared to integrate experts in the decision-making process which impeded the proper response to the Covid-19 crisis. The “soft” regulatory state seems an adequate intermediate option lying between the “hard” regulatory state model and a purer social state model. It offers protection of expertise through a consultative agency and integrates experts in the decision-making process without taking away from political organs the primary responsibility for, and, therefore, the democratic legitimacy of the decisions taken. In other words, and using an old expression, the experts are on tap, but not on top.

ABSTRACT: The Covid-19 crisis has rekindled the long-standing debate over the role of experts in policymaking. The pandemic is testing institutional frameworks throughout the world. This article explores the debate from an institutional perspective focusing on the EU and Spain. It analyses the EU’s common risk regulatory framework

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and then the institutional choices made to accommodate it. More specifically, the article explores the institutional proposal of the EU to address threats to human health, that is, its “soft” regulatory stance combining politics and expertise through consultative agencies. Then, the article analyses the Spanish management of the Covid-19 crisis and highlighting shortfalls of institutional design. In particular, the absence of an agency with reliable expertise, especially at the risk assessment stage, proved to be a disadvantage for crisis management in Spain because it opened space for intense crossfire and delegitimization. The contrast between the EU’s proposal and the Spanish experience managing the Covid-19 crisis shows that the “soft” regulatory model may be a suitable option for the design of institutional frameworks to address health threats.

KEYWORDS: Covid-19 crisis – risk analysis – regulatory state – agencies – expertise

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