The Covid-19 crisis: lessons from risk regulation for EU leaders

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Publication date
2020

Document Version
Final published version

Published in
EU Law Live. Weekend edition

The COVID-19 crisis: lessons from risk regulation for EU leaders

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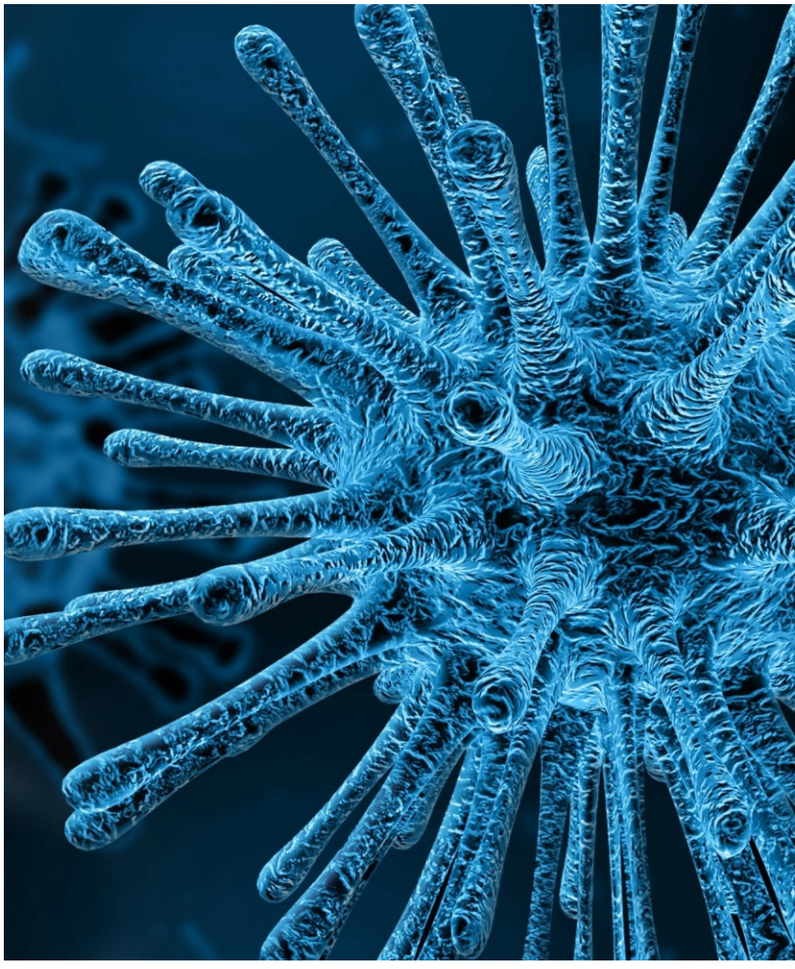
The European Union is living in a state of public health emergency. The COVID-19 epidemic is rapidly spreading across the EU causing a massive upheaval of public health systems, politics, economic relations, free movement and last, but not least, the lives of millions of people across the continent. According to the World Health Organization, COVID-19 is an international pandemic with 120,000 laboratory-confirmed cases so far, and 4,600 deceased worldwide.

The public health risk associated with a pandemic outbreak epitomises what Ulrich Beck and other sociologists of risk have referred to as late-modern, man-made or manufactured risks. This particular disease fits the bill in that it is arguably the result of globalisation and the diminishing space for - and human consumption of - wildlife. The management of such risks defines the structures of contemporary society, transforming it into what Beck calls the 'risk society.' The latter is defined by the paradoxical coexistence of progress and risk – while reaping the benefits of globalisation and technological progress, we are also increasingly faced with its negative side-effects and new contemporary risks that are not truly controllable nor fully measurable.



The COVID-19 outbreak displays all the characteristics of such late-modern risks, particularly due to the globalised context in which it takes place, which is key when we are trying to conceive of appropriate regula-

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tory responses. Such risks are often 'invisible,' which means that they evade human perceptive abilities and can only be identified through recourse to specialised science. The case of COVID-19 is such a risk, in that in terms of policy there is only the preparedness for the unknown – and now when the risk is manifesting, we are scrambling to understand its global magnitude and impact. At the same time, COVID-19 also painfully illustrates the distributional aspect of these types of risks – when their manifestation comes with enormous economic, social and human costs provoking conflicts over distribution and testing solidarity among people and states.

The good news is that unlike as Trump might have it, the European Union is a world leading risk regulator with a constitutional commitment to a high level of protection of public health and an institutional structure in place to address public health risks and emergencies. The bad news is that situations of scientific uncertainty and high politicisation make it very hard for the EU to play this role. The COVID-19 crisis presents a steep challenge to the EU as a risk regulator given the unprecedented level of the current emergency. The EU and Member States have to take decisions in the face of rapid spread of the disease, rapidly changing scientific information and therefore under considerable time pressure. How can the legal framework as developed in the context of EU risk regulation and public health help in guiding the EU's response?

The EU legal framework for EU public health emergencies

According to the EU Treaties, responding to public health emergencies, such as COVID-19, is primarily a responsibility of the Member States. EU action is limited to supporting, coordinating or complementing action by Member States, as well as adopting incentive measures and recommendations (Article 168 TFEU). This is due to limited EU competences in matters of health policy. However, EU action in the field of public health emergencies should be seen within the broader EU framework of public health law and policy. The EU commitment to ensuring a high level of human health protection in the definition and implementation of all its policies and activities is enshrined both in the Treaties and the EU Charter of Fundamental Rights.

Over the years, the EU's role in responding to public health emergencies has grown, especially as a result of the Anthrax scare in 2001 and the consecutive health scares of SARS and Bird Flu. In response to the last large scale event of the Swine flu outbreak, the EU regulatory system was boosted by the 2013 Health Threats Decision. The latter is applicable to a wide scope of public health emergencies (including bioterrorism and environmental risks) and formalises some of coordination and emergency management and decision-making procedures. The Decision incorporates an older Communicable Disease Early Warning and Response Mechanism (EWRS). It also institutionally formalises the Health Security Committee that encompasses a number of sub-groups including one on public health communication. The European Centre for Disease Control (ECDC) manages the Early Warning and Response Mechanism through which contact-tracing of infected individuals throughout the EU becomes possible and communications about disease outbreaks can be communicated in a closed system of national public health institutions. The ECDC is also regularly updating its risk assessment on COVID-19 situation in Europe. The health ministries are represented in the Health Security Committee which is chaired by the European Commission.

Under this framework Member States are obliged to inform the ECDC, the Health Security Committee and the European Commission of counter measures that are adopted at national level, ideally before these are implemented. Furthermore, urgent implementing measures can be taken by the European Commission for triggering the manufacturing and central authorisation of pandemic vaccines and other emergency medicines. For this purpose, the system also provides the Commission with the ability to declare an emergency in case the World Health Organisation has not done so. Cross-sectoral coordination is taking place in a more ad-hoc manner in that the European Commission established a 'COVID-19 response team', with five commissioners coordinating the work in different areas.

Furthermore, the Health Threats Decision foresees the possibility of voluntary public procurement of medicinal countermeasures and medical equipment. In the aftermath of the Swine Flu outbreak a mandatory system was intended to ensure EU solidarity in times of emergency and to respond to the vast asymmetries that occurred in the procurement of swine flu vaccines across the EU. However, in 2013, by the time the Swine Flu was already out of the regulators' minds, the Member States only agreed to sign on to a voluntarily system of public procurement. Currently 20 Member States have signed on to a tender for medical supplies, in order to prevent 'useless competition between EU Member States and prevent international speculation.'

Lessons from EU risk regulation

What are the lessons from EU risk regulation and its underlying principles, as developed through a long line of EU legislative and case law developments, for the current management of the COVID-19 outbreak in the European Union? The role of EU law, and of law more generally, in the face of scientifically complex and rapidly moving

developments, is to organise the process of how public decisions on risk should be taken. It is the adherence to such a legally mandated process that makes the outcome of decisions legitimate and acceptable. A fundamental principle of EU risk regulation is the principle of risk analysis, which mandates that every decision-making process on risk must consist of a scientific risk assessment, and a politically responsible and democratically legitimated risk management. It must also be accompanied by effective risk communication between and among public authorities and between the latter and citizens. The main purpose of the risk analysis principle is to ensure a balance between science and politics in risk regulation.

The risk assessment of COVID-19

A risk assessment is an essential procedural guarantee, which flows from the more general duty of care, and ensures scientific objectivity. It must be independent, excellent and transparent, and be carried out by scientific experts (Pfizer, T-13/99), mostly especially

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designated agencies, such as the ECDC. With regard to risk assessment the COVID-19 poses significant challenges, as there is no scientific certainty with regard to the precise nature of the risk. In this regard most national agencies are well informed and coordinated by the ECDC. However, the risk assessment in the case of COVID-19 clearly goes beyond the assessment of the hazard, namely the virus itself, but also includes questions concerning critical infrastructures (business continuity, availability of medical equipment, surge capacity of hospitals) and the way these will be affected in the Member States. Here it is clear that currently the EU Health Security structure is scrambling to play catch up. This challenge was already outlined in the evaluation of the Influenza A H1N1 outbreak, but in the meantime it is clear that risk assessment in this re-

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gard is highly fragmented and politicised, where not all Member States are eager to share how many antivirals they have stacked up in their stockpiles.

The risk management of COVID-19

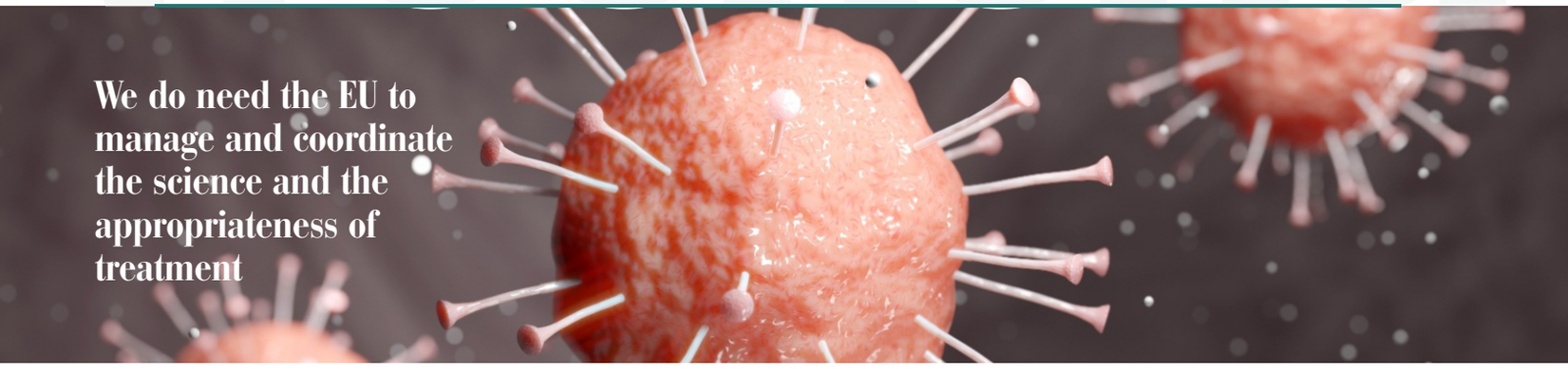
Following the Court of the European Union's case law, science must inform, but should not be the sole basis for making normative choices involved in public decision-making. It is the task of risk managers, considering scientific advice, to decide on whether action is warranted and what kind of action. This means often difficult, political and ethical choices, which can vary from one society to another according to the threshold of risk deemed acceptable. In other words, which risks societies are willing to accept, and what the levels of protection should be, is a decision for political institutions. In doing so, risk managers are obliged to ensure a high level of public health protection (Article 9 and Article 168 TFEU). They must also consider particular circumstances on a case-by-case basis, the severity of impact on public health, the reversibility of such impact, and the current perception of risk based on available scientific evidence (*Bayer*, T-429/13 and T-451/13).

Risk managers must consider the precautionary principle, a fundamental principle of EU risk regulation, and a general principle of EU law

Most critically, risk managers must consider the precautionary principle, a fundamental principle of EU risk regulation, and a general principle of EU law. It requires the authorities in question, to take appropriate measures to prevent specific potential risks to public health by giving precedence to the requirements related to the protection of those interests over economic interests (*Bayer*, T-429/13 and T-451/13). A situation of scientific uncertainty triggers the application of this principle. While a zero-risk approach is not allowed, the precautionary principle calls on the institutions to take protective measures without having to wait until the reality and seriousness of risks become fully apparent or until the adverse health effects materialise (*BSE*, C-157/96 and C-180/96). Moreover, precautionary measures have to be proportionate. In other words, they must be appropriate to contain and mitigate the outbreak and not more restrictive than necessary to achieve the ultimate objective of public health protection.

What role for EU leadership?

What we currently see is that many commentators and citizens are looking at the EU as a benchmark of whether their own country is taking the right precautions. However, legally the Member States have clearly chosen to only give the EU a limited role in this respect, for example when it comes to ensuring the availability of a centrally authorised vaccine. As a consequence, it is to be expected that once vaccines become available, a situation similar to the Swine Flu H1N1 outbreak will occur, where some Member States through pre-purchase agreements bought up all the vaccines available for the whole of the EU. Another area where we might expect contention is when the EU will give guidance for the determination of risk-groups for vac-



We do need the EU to manage and coordinate the science and the appropriateness of treatment

cination and the treatment of the virus with antivirals. During Swine Flu (which might be considered a dry-run for what we are facing today) Member States did not all follow the EU's advice on risk groups and treatment protocols, which caused a lot of distrust and unrest among the population.

At the same time, we would not find it desirable for the EU to fully take charge of the risk management in the Member States. And many calls for a simplistic centralisation of coordination and health powers at EU level are disregarding the vast complexity of organising public health and healthcare at Member State level that goes far beyond the issues of redistribution of public finances. If the EU was to oblige the Member States to order a particular vaccine for medical countermeasures or to take a certain precautionary approach, it would not be able to consider these intricate differences. The (public) health systems in the Member States differ vastly, even within the states due to federation, culture, availability of resources, training of staff, equipment and the upkeep of critical infrastructures in general. So here we see the Member States adopt very different responses. Which is to be expected. So why would we need the EU then in a risk management role?

We do need the EU to manage and coordinate the science and the appropriateness of treatment. We also need the EU to organise solidarity through a mandatory system of public procurement of medicinal equipment and medicines; and we even need the EU to make the choice as to who – what countries – receive these items first. In other words, we could use the EU to organise solidarity among Member States, even when this means having the highly political role of determining risk groups and treatment plans, and being able to dish out vaccines and antivirals. This would rationalise the response and ensure its efficiency and effectiveness. The more proactive stance of the EU this week is a good sign in this respect. However, on all other aspects, the Member States should remain in charge of risk management in public health emergencies.

When national governments and public authorities manage COVID-19 risks, they should be clear about their political responsibility. While it is the task of risk assessors to communicate scientific advice including uncertainty information transparently, risk managers have to be transparent about political choices. Politicians must be able to take political responsibility for action, explain clearly which legal, political, ethical,

or socio-economic considerations inform their actions next to scientific advice. They should not hide behind science, nor act as scientific experts. Risk assessment and risk management are often intertwined in practice, but the responsibilities are clear. Democratically elected politicians, not scientists, will be held responsible for how they handle the COVID-19 crisis.

The COVID-19 crisis puts Europe's capacity to govern both effectively and legitimately to a test. It sheds light on the unique features of the European integration project (such as its commitment to unity in diversity), as well as unleashes some of its darker tendencies. Like in other situations of uncertainty and political and economic upheaval, this crisis can be both a threat to and an opportunity for European integration. Will Europe's response to COVID-19 unleash negative dynamics of populism and protectionism, or will it strengthen the EU system of public health governance, and more generally, the EU's sense of collective identity and solidarity? Let us hope so. The EU is at a crucial point and further actions will determine which direction will be taken.

References for further reading:

Maria Weimer, Risk regulation in the Internal Market - Lessons from Agricultural Biotechnology (Oxford University Press, 2019)

Maria Weimer, The Origins of 'Risk' as an Idea and the Future of Risk Regulation, *European Journal of Risk Regulation* 8 (2017), p. 10

Mark Flear & Anniek De Ruijter, Guest Editorial to the Symposium on European Union Governance of Health Crisis and Disaster Management: Key Norms and Values, Concepts and Techniques, *European Journal of Risk Regulation 10* (2019)