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# *Break or Bend in Case of Emergency?: Rule of Law and State of Emergency in European Public Health Administration*

Filipe Brito BASTOS\* and Anniek DE RUIJTER\*\*† 

*In this article, we ask what the impact is of the role of the EU administration in responding to emergencies in terms of (changes to) the rule of law. A response to an emergency in some cases creates exceptions to rule of law guarantees that bind the authorities to procedural rules and fundamental rights. These exceptions can become more permanent and even change the constitutional order of the EU. We articulate the legal framework for health emergencies, and discuss how the EU court has interpreted and developed this framework in two key decisions. We then ask whether this framework offers adequate safeguards for upholding the rule of law in cases of major health emergencies. We conclude that public health emergencies can bend and even break rule of law requirements for the EU administration, and advocate for more legal guidance on proportionality, which may offer better safeguards suited for protecting the rights of affected parties.*

## I. INTRODUCTION: EMERGENCIES AND THE EU ADMINISTRATION

Emergencies for a legal system often sound “the hour of the executive”. In an immediate and urgent situation, such as disease outbreaks, food contaminations, terrorist attacks, and large-scale natural disasters, there is not usually sufficient time to wait for legal proceedings or a parliamentary debate. For that reason, EU law confers a wide margin of executive discretion to take urgent measures on the authorities involved at various levels of EU administrative system – if need be, even by derogating from the applicable legislative provisions. Such powers have been long enjoyed by the Commission,<sup>1</sup>

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<sup>1</sup> See the CJEU’s old ruling in Case 23-75, *Rey Soda*, EU:C:1975:142, where at para 11 the conferral of “wide powers of discretion” onto the Commission is justified in view of it being able to continually monitor the implementation of policies and “act with urgency as the situation requires”.

national authorities,<sup>2</sup> and more recently, though not without serious constitutional doubts, by EU agencies as well.<sup>3</sup>

However, the EU's involvement in emergencies poses a number of challenges for its legal system, particularly relating to adherence to the rule of law principles. While in some cases these challenges may be prompted and even justified by highly pressing emergencies, they also may occur in less high-profile situations. Indeed, as Waldron has shown, many of today's concerns about public power being unbound from the rule of law do not relate to its most extreme examples – such as the Guantanamo detention facilities – but to rather more prosaic problems concerning public administration.<sup>4</sup> In the US, an intense debate has been reignited as to whether the seeming abdication of US courts from adequately reviewing the rising administrative state complies with the rule of law.<sup>5</sup> In the EU, similar concerns about public power beyond the rule of law are raised by the fact that, emergencies tend to sideline representative and democratic actors, can trigger momentum for legal changes that then become normalised,<sup>6</sup> and more generally have led to a remarkable expansion of administrative powers with fewer legal constraints.

The formal requirement of deciding by procedure is not a mere technicality. Administrative procedures, through formal steps and phases, limit the possibility for arbitrary, misinformed, or excessive use of power. This is why, as Jhering famously put it, “form is the sworn enemy of arbitrariness, the twin sister of liberty”.<sup>7</sup> And yet, European Union law foresees a growing number of instances where, in cases of emergency, the law itself unshackles the power of European administration from the formal and procedural limits imposed by administrative law. This significantly diminishes the legal guarantees required by the rule of law. If the powers that the legislation confers to European administration do not break the rule of law, they do at the very least bend it.

In this article, we ask what the impact is of the role of the EU administration in responding to public health emergencies in terms of the rule of law. The aim of public health – the protection of the health of population from the risk of unsafe foods or medicines, or the spread of infectious disease – has already proven in the past to lead to a form of “institutionalised exceptionalism”.<sup>8</sup> In an emergency the

<sup>2</sup> The first legislative instruments on the common agricultural policy provided for urgent measures in case of abrupt shifts in market prices. See for instance Art 22 of Regulation 19/62, on the progressive establishment of a common market in cereals.

<sup>3</sup> See Case C-270/12, *United Kingdom v European Parliament and Council*, EU:C:2014:18, where the powers of the European Markets and Securities Authority to address certain emergencies in financial markets were challenged by the British government.

<sup>4</sup> J Waldron, *The Rule of Law and the Importance of Procedure*, New York University Public Law and Legal Theory Working Papers, Paper 234 (2010) p 17.

<sup>5</sup> See P Hamburger, *Is Administrative Law Unlawful?* (University of Chicago Press 2015) and A Vermeule, *Law's Abnegation: From Law's Empire to the Administrative State* (Harvard University Press 2016).

<sup>6</sup> D Curtin, “Challenging Executive Dominance in European Democracy” (2013) 77(1) *Modern Law Review* 1.  
S Gabriel Knowles, “Learning from Disaster?: The History of Technology and the Future of Disaster Research” (2014) 55 *Technology and Culture* 773.

<sup>7</sup> R von Jhering, *Geist des Römischen Rechts auf den verschiedenen Stufen seiner Entwicklung*, II, 2nd edn (Breitkop & Härtel 1875) pp 471–472.

<sup>8</sup> L Bengtsson and M Rhinard, “Securitisation across Borders: The Case of “Health Security” Cooperation in the European Union” (2019) 42 *West European Politics* 346.

existing administrative processes might be set aside in favour of swift action, which may lead to new working methods, regulations or decision – many of which come to produce a lasting impact in shaping the EU’s legal order and in fact become an integral and permanent part of its administrative framework.<sup>9</sup> The institutional and legal legacy of the BSE crisis, and the ways in which it decisively shaped EU food safety law, is just one of many possible examples.<sup>10</sup>

Our main argument is that the current framework, and the interpretation and application thereof by the EU Court, allows space for the EU administration to bend and even break the key rule of requirements. We examine in particular the right to be heard and the duty of care, two procedural requirements that must by their nature be respected *during* a decision-making procedure, but the observance of which may be difficult in view of the need for authorities to come to decisions urgently in cases of emergency. While in extreme cases it may be impossible for such important procedural requirements to be fulfilled, we argue for a differentiated approach, where the response may vary depending on, and should be proportionate to, the nature and extent of the emergency, with a view to protecting the interests of affected parties.

The article proceeds as follows. We first develop an analytical framework based on constitutional theory and EU administrative law, outlining the requirements and rationale behind safeguarding or bending and breaking the rule of law’s requirements in times of emergency (section II). In doing so, we consider two particularly revealing rulings of the Court of First Instance and the CJEU that address how those requirements may need to be lessened in public health emergencies (section III). We then proceed in light of the constitutional and administrative law framework resulting from the preceding theoretical and doctrinal considerations, to analyse the Decision on Serious Cross-Border Threats to Health (“Health Threats Decision”),<sup>11</sup> with the objective of testing the limits of the CJEU’s own case law once it is generalised to cases where a larger part of the population could be affected (section IV). Last, we zoom in on proportionality as a leading principle for administrative actors to consider in bending or breaking the right to be heard and the duty of care (section V).

## II. ANALYTICAL FRAMEWORK: FROM CONSTITUTIONAL CONUNDRUM TO ADMINISTRATIVE LAW

Emergencies create constitutional conundrums for rule of law theory in two ways. The first is that sometimes administrative or executive action needs to be taken that is not foreseen by law. This poses a challenge to legal systems in light of the rule of law principle that holds that every exercise of public power must be bound by law. The

<sup>9</sup> J White, “Emergency Europe” (2015) 63 *Political Studies* 300; J White, “Authority after Emergency Rule” (2015) 78 *The Modern Law Review* 585; M Dawson and F de Witte, “Constitutional Balance in the EU after the Euro-Crisis” (2013) 76 *The Modern Law Review* 817; M Dawson et al, *Beyond the Crisis: The Governance of Europe’s Economic, Political and Legal Transformation* (Oxford University Press 2015).

<sup>10</sup> E Vos, “EU Food Safety Regulation in the Aftermath of the BSE Crisis” (2000) 23 *Journal of Consumer Policy* 227.

<sup>11</sup> “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” (OJ L 293/1 5–11 2013).

second way that an emergency can pose a constitutional conundrum, is that it may require that the protection of the individual's rights be balanced with the protection of the population under conditions where little time is available to find the most balanced solution. In this case, the protection of individual rights can be diminished in view of the need to take urgent action to protect the population.

There are generally two theoretical ways in which a constitution can address these conundrums. In the first ("absolute") approach, emergency powers are used beyond the legal order. In the second ("relative") approach, the powers used are regulated within the constitutional order.<sup>12</sup>

The first manner is to hold situations of emergency to be so exceptional that we have to accept that the law does not, or cannot, provide the solution, and does not prescribe legal procedures that would inhibit the executive's ability to safeguard the population. Put differently, the emergency is seen as standing beyond the sphere of the constitution, beyond the law itself. On this point, Carl Schmitt's account of the state of exception and its relation to sovereignty has exerted a lasting influence on contemporary debates. In his quest for the true locus of sovereignty, Schmitt found that the person or public authority that is able to declare a state of exception is the true sovereign. In modern literature, a version of solving the conundrum in this manner has been advocated by Oren Gross, who outlines an "extra-legal measures model" that, by his account, safeguards the rule of law from a constantly "bending" the law to accommodate emergencies.<sup>13</sup> This way, "going outside the rule of law in appropriate cases may preserve, rather than undermine the rule of law".<sup>14</sup>

The second, "relativist" approach to the above conundrums is to bring governance in cases of emergencies *within* the law. This approach, supported by Dyzenhaus, is rather to "govern through law in an emergency" instead of going "outside" the rule of law.<sup>15</sup> In this approach the law foresees certain emergency measures. In this case the legal protections of individuals can also be diminished and the administrative and legal procedures may be less strict. Yet, crucially, the confines of the state of emergency are determined and constrained by the law itself, from an internal perspective; there is a compulsion of legality that is felt by the administration.<sup>16</sup>

However, neither theory necessarily accounts for the reality of how legal systems deal with emergencies and disasters, particularly not in a multilevel setting. Here the distinction of what may count as an emergency – the nature of the emergency – is important. Some emergencies may be completely unforeseeable and uncontrollable, whereas other emergencies may cause imminent threats to public health and the environment, but can be addressed by systems in place to respond to these threats.<sup>17</sup> The first "disaster" situation might require the setting aside of law. However, the second kind of emergency represents continuity between ordinary and extraordinary

<sup>12</sup> A Fioritto, *L'amministrazione dell'emergenza tra autorità e garanzie* (Il Mulino 2008) p 30.

<sup>13</sup> O Gross, "Extra-Legality and the Ethic of Political Responsibility" in VV Ramraj (ed), *Emergencies and the Limits of Legality* (Cambridge University Press 2008) p 62.

<sup>14</sup> Gross, *supra*, note 13.

<sup>15</sup> D Dyzenhaus, "The Compulsion of Legality" in Ramraj, *supra*, note 13, p 33.

<sup>16</sup> *ibid*, p 39.

<sup>17</sup> See *ibid*, pp 25, 237–240.

circumstances, is “legitimised by a legality of emergency”,<sup>18</sup> which usually means that the executive is empowered to exercise broader authority.<sup>19</sup> This means many emergencies need not be threats to the constitutional order as such and are addressed by administrative agencies rather than high-level political actors setting aside the constitution.

### 1. Public health emergencies and the rule of law in European administration

A state of emergency, where the law is set aside, is generally a derogation from the rule of law. The rule of law is often described as an essentially contested concept, in that disputes over its content and implications are too severe for any agreement to be possible,<sup>20</sup> and in spite of some variation across jurisdictions as to what it means,<sup>21</sup> distinct versions of the concept of the rule of law appear to be unified in at least two aspects.

First, the rule of law reflects, at the bare minimum, a common concern that public power be confined by clear legal boundaries, predictable for individuals,<sup>22</sup> and reviewable by independent courts.<sup>23</sup> The rule of law demands laws to constitute standards capable both of guiding the behaviour of its subjects and of preventing the arbitrary or excessive use of public power.<sup>24</sup> These are all ideas present in EU constitutional law,<sup>25</sup> which enshrines the rule of law as a founding principle applying both to the EU and its Member States.<sup>26</sup>

Second, the various versions of the rule of law were born out of fear of the excesses of executive power. They all originate in the same demand that the *executive* in particular be subject to laws – to the sovereign will of the people, as expressed by the legislature.<sup>27</sup> Indeed, of all branches of government, it is the executive in particular that raises the most concerns of abuse of power. Throughout history, the executive branch has shown a drive towards the expansion of its own power. It has tended to seize the opportunities to do so that appear in times of war or emergency.<sup>28</sup> This is why, in

<sup>18</sup> *ibid*, p 240.

<sup>19</sup> *ibid*, pp 240–243.

<sup>20</sup> J Waldron, “The Rule of Law and the Importance of Procedure” in J Fleming, *Getting to the Rule of Law* (New York University Press 2011) p 3.

<sup>21</sup> M Loughlin, *Foundations of Public Law* (Oxford University Press 2010) p 312 ff.

<sup>22</sup> J Waldron, “The Rule of Law in Public Law” in *New York University Public Law and Legal Theory Working Papers* (New York University School of Law 2014) p 1 at p 12. See also B Tamanaha, *On the Rule of Law: History, Politics, Theory* (Cambridge University Press 2004) p 91 ff on the requirement of predictability and other formal aspects of the rule of law.

<sup>23</sup> Waldron, *supra*, note 20.

<sup>24</sup> J Raz, “The Rule of Law and its Virtue” in *The Authority of Law: Essays on Law and Morality* (Clarendon 1979) pp 210 ff, 214–218 and B Tamanaha, “A Concise Guide to the Rule of Law” in G Palombella and N Walker (eds), *Relocating the Rule of Law* (Hart Publishing 2009) p 3, at pp 3–6.

<sup>25</sup> One seminal example of this is Joined Cases 46/87 and 227/88, *Hoehchst*, EU:C:1989:337.

<sup>26</sup> See Art 2 TEU and Cases 294/83, *Parti écologiste “Les Verts”* EU:C:1986:166 and C-2/88, *Zwartveld*, EU:C:1990:315, paras 16–17. On the principle of the rule of law in the EU, see K Lenaerts, “The Rule of Law and the Coherence of the Judicial System of the European Union” (2007) 44 *Common Market Law Review* 1625.

<sup>27</sup> H Klecatsky, “Reflections on the Rule of Law and in Particular the Principle of Legality of Administrative Action” (1963) 4 *International Commission of Jurists* 205, at p 209.

<sup>28</sup> R Alford, *Permanent State of Emergency, Unchecked Executive Power and the Demise of the Rule of Law* (McGill-Queen’s University Press 2017) at pp X and 12–13.



continental legal traditions, the emergence of the rule of law cannot be dissociated from the incremental development of administrative law.<sup>29</sup>

## 2. The rule of law purpose of administrative rights of the defence

In the EU, as in many other legal systems, the somewhat abstract notion of the rule of law is given specific meaning in the requirement that the administration exercises its authority pursuant to administrative procedures. The administration must follow a pre-established order of phases, where different steps and acts lead to the adoption of a final decision.<sup>30</sup> By laying down administrative procedures, the law promotes rationality in the administration's and executive's decision-making, as it becomes structurally conditioned to act according to the desires of the legislature.<sup>31</sup> The administration is legally obliged to consider opposing interests in order to come to an informed conclusion on how to decide in a given case.<sup>32</sup> It must combine considerations of how to fulfil policy goals effectively, and how to respect the position of those individuals affected by its decision.<sup>33</sup> This concern to balance policy and private interests also pervades the procedures of Europe's administrative system.<sup>34</sup> By binding authorities to following a pre-established sequence of steps and phases where different tasks must be fulfilled, administrative procedures limit the chances for power to be exercised arbitrarily.<sup>35</sup>

In the EU, some such steps, tasks, and procedural phases are covered by a general constitutional principle that is described in the case law as the principle of the "rights of the defence". Such rights, which include the right of individuals to a fair hearing and the administration's duty of care, constitute individual procedural guarantees that oblige the administration to carefully consider all relevant interests in order to reach an informed and balanced decision. They fulfil an objective purpose; of enhancing the quality of administrative decision-making, as well as a subjective purpose; of protecting private parties from irrational or misinformed exercises of public power. In the EU's legal order, both are aims that are strictly linked to the rule of law.<sup>36</sup>

<sup>29</sup> As Sordi explains, the emergence of administrative law responded to the need to "circumscribe the enormous power that executive administrations had conquered with the French revolution and the Napoleonic era": B Sordi, "Révolution, Rechtsstaat and the Rule of Law: historical reflections on the emergence of administrative law in Europe" in S Rose-Ackerman and P Lindseth (eds), *Comparative Administrative Law* (Edward Elgar 2010) p 23, at p 29.

<sup>30</sup> G della Cananea, *Due Process of Law beyond the State: Requirements of Administrative Procedure* (Oxford University Press 2016) p 22.

<sup>31</sup> J Barnes, "Sobre el Procedimiento Administrativo: Evolución y Perspectivas" in J Barnes (ed), *Innovación y Reforma en el Derecho Administrativo* (Global Law Press 2006) p 261, at pp 270–271.

<sup>32</sup> della Cananea, *supra*, note 30, p 19.

<sup>33</sup> H Pünder, "Administrative procedure – mere facilitator of material law versus cooperative realisation of common welfare" in H Pünder and C Waldhoff (eds), *Debates in German Public Law* (Hart Publishing, 2014) p 239, at p 240.

<sup>34</sup> H-C Röhl, "Procedures in the European Composite Administration" in J Barnes, *Transforming Administrative Procedure* (Global Law Press 2008) p 77, at p 79 ff.

<sup>35</sup> della Cananea, *supra*, note 30, p 34.

<sup>36</sup> HP Nehl, *Principles of Administrative Procedure in EC Law* (Hart Publishing 1999) p 2. See also T Tridimas, *The General Principles of EU Law*, 2nd edn (Oxford University Press 2006) p 371 and J Mendes, *Participation in EU Rule-Making: A Rights-Based Approach* (Oxford University Press 2011) p 33.

Indeed, the EU's understanding of the constitutional principle of the rule of law strongly emphasises formal and procedural values.<sup>37</sup> It is therefore unsurprising that the CJEU considers the rights of the defence to constitute a fundamental principle of Union law "which must be guaranteed even in the absence of any rules governing the proceedings in question".<sup>38</sup> Even if the legislation is silent on whether the administration must hear affected parties before making a decision, or carefully collect and assess all relevant facts, EU constitutional law requires such a hearing to be ensured, or that the facts of the case be handled in that manner. The disregard of such procedural guarantees constitutes an infringement of an essential procedural requirement in the sense of Article 263 TFEU, which the CJEU may even scrutinise on its own motion.<sup>39</sup>

For the purposes of the present article, two rights of the defence in EU administrative law are particularly relevant, as the nature of health emergencies often involves ethical issues and a need to base decisions on scientific input and expert advice. Those rights are the right to be heard and the administration's duty of care. The reason why the two constitute two important test cases for the balancing between rights of the defence and the need to swiftly address a public health emergency is that they are both rights which – unlike the right to a reasoned decision, or indeed unlike the right to an effective judicial protection – must typically be exercised *before* an authority takes a decision. Yet the fact that so little time is normally available in urgent decision-making leaves very few room for the rights to be exercised at all.

#### *a. The right to a fair hearing*

Though many formulations have been used over time to refer to what it actually entails,<sup>40</sup> the right to a fair hearing, also known as the right to be heard, involves the right of private parties to defend their views before the conclusion of an administrative procedure that is likely to result in a decisional outcome that adversely affects them.<sup>41</sup> In essence, what is required of the administration is that it provides its subjects with an opportunity to effectively influence the decision-making process.<sup>42</sup> This is a right that is enshrined in

<sup>37</sup> L Pech, "A Union Founded on the Rule of Law: Meaning and Reality of the Rule of Law as a Constitutional Principle of EU Law" (2010) 6(3) *European Constitutional Law Review* 359, at p 372. See however J Raitio, "Does the concept of rule of law have any material content? A Nordic point of view" (2017) 24(6) *Maastricht Journal of European and Comparative Law* 774, at pp 786–789.

<sup>38</sup> The rulings emphasising this point are legion. For many, see Case C-32/95 P, *Lisrestal*, EU:C:1996:402, para 21; Case T-334/07, *Denka*, EU:T:2009:453, para 127; and Joined Cases T-91/12 and T-280/12, *Flying Holding*, EU:T:2014:832, para 54.

<sup>39</sup> See, for instance, Cases C-291/89, *Interhotel*, EU:C:1991:189, para 14; C-367/95 P, *Sytraval*, EU:C:1998:154, para 67; C-286/95 P, *Imperial Chemical Industries*, EU:C:2000:188, para 51; and T-240/10, *Hungary v Commission*, EU:T:2013:645, para 70.

<sup>40</sup> See the contribution of I Rabinovici, "The Right to Be Heard in the Charter of Fundamental Rights of the European Union" (2012) 18(1) *European Public Law* 149.

<sup>41</sup> For many, see Case T-260/11, *Kingdom of Spain v Commission*, EU:T:2014:555, paras 62–63 and C-418/11, *Texdata*, EU:C:2013:588, para 83.

<sup>42</sup> See Joined Cases T-191/98, T-212/98 to T-214/98, *Atlantic Container Line*, EU:T:2003:245, para 138. See also D Curtin, "Constitutionalism in the European Community. The Right to Fair Procedures in Administrative Law" in *Human Rights and Constitutional Law. Essays in Honour of Brian Walsh* (Round Hall Press 1992) p 293, at p 301 and E Barbier de la Serre, "Procedural Justice in the European Community Case-law concerning the Rights of the Defence: Essentialist and Instrumental Trends" (2006) 12(2) *European Public Law* 225, at p 233.



Article 41(2)(a) of the Charter of Fundamental Rights.<sup>43</sup> Historically, it was incorporated into EU constitutional law by the Court of Justice,<sup>44</sup> which held it to be a “fundamental principle” of the EU’s legal order.<sup>45</sup>

The right to be heard is enshrined in various ways in EU legislative instruments that establish administrative emergency powers. One can identify at least three models. In some administrative procedures, no reference at all is made to hearing. In the second model, it is left to public administration to decide whether it wishes to provide a hearing as a matter of discretionary choice. A third type of urgent administrative procedure combines a purely discretionary choice to provide a hearing *during* the procedure with an obligation to provide a hearing *after* the final decision has been adopted.

First, some instruments providing for administrative powers of emergency do not address issues of participation of affected parties at all. EU food safety law, for example, establishes urgent administrative procedures whereby, at its own initiative or upon the request of a Member State, the Commission can adopt urgent provisional decisions meant to address serious risks posed by a foodstuff.<sup>46</sup> Such decisions can consist, for instance, in the provisional suspension of the placing on the market or use of the food in question. If the Commission fails to act upon a request for urgent measures from a Member State, that state’s authorities may themselves adopt provisional measures which can be maintained until there has been a final decision at EU level. The Commission has ten days to take a final decision by confirming, extending, revoking, or amending the provisional measures, regardless of whether they were initially taken by the Commission itself or by national authorities.<sup>47</sup> It is striking how, even though they may be negatively affected by measures of this kind, market actors do not benefit from any provision ensuring their right to be heard.

An example of the second model is the EU’s legal framework for the marketing of pharmaceuticals. That framework provides for a procedure for cases where a Member State considers that “urgent action is essential to protect human health or the environment”.<sup>48</sup> In such cases, the Member State’s competent authority for medicinal

<sup>43</sup> Some authors dispute the extent to which the wording of the provision in the Charter actually corresponds to the formulations used in prior case law. See Rabinovici, *supra*, note 40.

<sup>44</sup> K Lenaerts and J Vanhamme, “Procedural Rights of Private Parties in the Community Administrative Process” (1997) 34 *Common Market Law Review* 531, at p 568.

<sup>45</sup> See for instance Cases 17-74, *Transocean Marine Paint*, EU:C:1974:91, para 15; 136/79, *National Panasonic*, EU:C:1980:169, para 21; 85/87, *Dow Benelux*, EU:C:1989:379, para 25; and C-204-5/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P, *Aalborg Portland*, EU:C:2004:6, para 64.

<sup>46</sup> See Arts 53 (1) and (2) and 54 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. The Court has had the opportunity to clarify that the Commission is not *required* to adopt such measures upon the request of a Member State where the risks to human health, animal health, or the environment, are not evident (Case C-111/16, *Fidenato*, EU:C:2017:676, para 30). The urgent measures at stake must be “based on a risk assessment as complete as possible in the particular circumstances of an individual case” (Joined Cases C-58/10 to C-68/10, *Monsanto*, EU:C:2011:553, para 77).

<sup>47</sup> It is worth pointing out that these administrative procedures are also applicable in cases involving genetically modified food and feed (see Art 34 of Regulation 1829/2003).

<sup>48</sup> Art 20 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

products may suspend the use of a given drug within its territory until the Commission, after requesting an opinion from the European Medicines Agency, takes a final decision on the matter. The Regulation is silent as to whether the national authority must offer a hearing before it adopts the interim measures to suspend the use of the medicinal product. As for the Commission, it only has to invite the holder of the authorisation to market the pharmaceutical to provide oral or written explanations whenever it considers that such would be “practicable”.<sup>49</sup> Such practicability might relate to the urgency of the situation.

The third model balances procedural protection with the need for urgent action, by allowing the administration not to conduct hearings *during* the decision-making process, but nevertheless requiring it to give affected parties an opportunity to express their views *after* the decision is adopted. An illustration of this model is found in the Framework Regulation of the Single Supervisory Mechanism (SSMFR).<sup>50</sup> According to Article 31(4) SSMFR, whenever “an urgent decision appears necessary in order to prevent significant damage to the financial system”, the ECB may adopt a “supervisory decision addressed to a party which would adversely affect the rights of such party without giving the party the opportunity to comment on the facts, objections and legal grounds relevant to the ECB supervisory decision prior to its adoption”. Once the supervisory decision is taken, however, the affected credit institution must be given that opportunity “without undue delay”.<sup>51</sup>

#### *b. The duty of care*

The duty of care is a procedural obligation that the administration must fulfil, particularly so when it enjoys discretionary powers. Though the provisions on the fundamental right do not allude to it, the duty is broadly taken to have been implicitly codified in the right “to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union” (Article 41(1) CFR).<sup>52</sup> The duty of care, also known as the duty of diligent and impartial examination of the case, has been developed in the case law since the *Nölle* case.<sup>53</sup> Since then, the case law – mostly stemming from the General Court – has emphasised that:

“[...] where the institutions have a broad discretion, respect for the rights guaranteed by the legal order of the European Union in administrative procedures is of even more fundamental importance; those guarantees include, in

<sup>49</sup> Art 20(3) Regulation (EC) No 726/2004.

<sup>50</sup> Regulation (EU) No 468/2014 of the European Central Bank of 16 April 2014 establishing the framework for cooperation within the Single Supervisory Mechanism between the European Central Bank and national competent authorities and with national designated authorities (SSM Framework Regulation).

<sup>51</sup> Art 31(5) SSMFR.

<sup>52</sup> B Mihaescu, *The Right to Good Administration at the Crossroads of the Various Sources of Fundamental Rights in the EU Integrated Administrative System* (Nomos 2015) pp 392 and 463 and H Hofmann and B Mihaescu, “The Relation between the Charter’s Fundamental Rights and the Unwritten General Principles of EU Law: Good Administration as the Test Case” (2013) 9(1) *European Constitutional Law Review* 73, at p 92. In the case law, see Case T-731/15 *Klyuyev*, EU:T:2018:90, para 103.

<sup>53</sup> Case C-16/90, *Nölle*, EU:C:1991:402.

particular, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case”.<sup>54</sup>

The relevance of the duty of care can only be truly understood in the light of the fact that the EU judicature cannot review the substance of discretionary decisions. Discretion can therefore only be subject to judicial review by reference to the factual or legal basis or by reference to the rules of procedure which govern the decision-making process. The duty of care functions as a standard that judges can apply to determine whether the administration was diligent in collecting and in assessing the information needed to appraise the factual and legal aspects of a given situation.<sup>55</sup>

### III. RIGHTS OF DEFENCE IN PUBLIC HEALTH EMERGENCIES: PRACTICE OF THE EU COURTS

The observance of the rights of the defence in situations of health emergency is particularly difficult. EU law generally offers broad discretion to EU authorities in such situations, and the CJEU exercises only a limited degree of control with regard to the substantive reasons for decisions within the realm of the discretion of the administration. In this regard the notoriously broad discretion that EU law confers to national and EU authorities in situations of emergency is particularly difficult to reconcile with the observance of rights of defence.

On the one hand, as was pointed out before, the CJEU requires – as a matter of the rule of law<sup>56</sup> – that the *right to be heard* be observed even in the absence of specific legislative provisions. Yet, the case law of EU courts shows that the protection of the right to be heard is significantly more complex in contexts of emergency. Identifying the parties affected by urgent decisions, notifying them of the opportunity to make their views known in person or in writing, giving them the time to prepare their observations, and processing the information they provide, are all steps that require time. For that reason, whenever there is an imminent threat to important public interests such as public health or the protection of the environment, the EU Court requires the right to be heard to be weighed against the need for urgent administrative measures.

The *duty of care*, on the other hand, requires the *factual* basis for administrative action to be as complete and accurate as possible, and that the administration is thorough in how it gathers and appraises information before it exercises any discretionary powers.<sup>57</sup> Yet, in order to do so, the administration needs time. In emergencies, by definition, time is of the essence and in short supply. The administration may not

<sup>54</sup> Cases T-443/11, *Gold East Paper*, EU:T:2014:774, para 123; T-355/13 *easyJet*, EU:T:2015:36, para 19; and T-574/14, *European Association of Euro-Pharmaceutical Companies*, EU:T:2018:605, para 76. See also Case C-269/90, *Technische Universität München*, EU:C:1991:438, para 14.

<sup>55</sup> Cf J Mendes, “Discretion, Care and Public Interests in the EU Administration: Probing the Limits of the Law” (2016) 53(2) *Common Market Law Review* 419, at p 431 ff.

<sup>56</sup> See Opinion of AG Poiares Maduro in Joined Cases C-402/05 P and C-415/05 P, *Kadi*, EU:C:2008:11, para 49 and, more recently, the General Court’s ruling in Case T-138/14, *Randa Chart*, EU:T:2015:981, para 112.

<sup>57</sup> For an overview of the case law developing the duty of care, see P Craig, *EU Administrative Law* (Oxford University Press 2012) p 333 ff.

always have the time to take pause at all the factual elements it needs to make an informed decision or, for that matter, to double-check the accuracy of the information it receives from its counterparts in settings of emergency.

The following section examines how the CJEU has balanced the rights of defence with the need to take urgent measures to address public health emergencies. The *Dokter* ruling illustrates how the CJEU addresses the right to be heard in cases of emergency. The ruling represents a model that can be generally described as a way of bending of the rule of law's demands which, though admissible in abstract, may in concrete cases may lead to unnecessary and disproportionate restrictions to the right to be heard. The *Malagutti-Vezinhet* ruling, by contrast, addresses the administration's duty of care in a manner that leaves little leeway for that duty to be fulfilled even at a minimal level. It will be argued, therefore, that the CJEU's model to balance the duty of care with the needs of public health emergencies constitutes an actual breaking of the rule of law.

### 1. The *Dokter* case

The *Dokter* Case provides the CJEU with an opportunity to clarify how the right to be heard should be reconciled with the need for urgent measures in cases of emergency when legislation is silent on the matter. In essence, the *Dokter* ruling closely resembles the current regime of urgent measures in relation to financial system in the Single Supervisory Mechanism's Framework Regulation (see section II.3.a).

Following an outbreak of foot-and-mouth disease, Dutch authorities ordered the slaughter of the cattle owned by Dokter and a number of other farmers for the simple reason that their proximity of their holdings to the location of outbreak raised the suspicion of further contamination.<sup>58</sup> The decisions were taken based on the laboratory results of exams carried out on cows at a nearby farm.<sup>59</sup> Dokter and the other claimants in the main proceedings claimed not to have been afforded the opportunity to contest the evidence that the Dutch administration used in support of its decisions, and that the right to be heard had therefore not been respected.

In its ruling in the *Dokter* judgment, the Court held that the right to be heard had not been breached. While recalling the constitutional importance of procedural rights – and that they should in principle be ensured even where the legislation does not provide for their exercise – the Court also emphasised that, as with other fundamental rights, the right to be heard could be subject to proportionate limitations.<sup>60</sup> Given that the disease outbreak required immediate preventive measures, the observance of procedural rights to their fullest – giving the affected parties an opportunity to be heard *before* the decisions were taken – *would have defeated the very point of the Directive*.<sup>61</sup>

<sup>58</sup> Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease.

<sup>59</sup> Case C-28/05, *Dokter*, EU:C:2006:408.

<sup>60</sup> *Dokter*, supra, note 59, paras 74–75; T Duijkersloot, “Consequences of the Violation by Administrative Authorities of the Right to be heard under EU Law: the Case M.G. and N.R.” (2014) 7(1) Review of European Administrative Law 81, at p 89. See also Case C-418/11, *Texdata Software*, EU:C:2013:588, paras 83–84; C-383/13 PPU, *MG and NR*, EU:C:2013:533, para 33.

<sup>61</sup> As the Court put it, “if the competent authority were not able to take measures against foot-and-mouth disease unless all potentially concerned parties had previously been given the opportunity to familiarise themselves with the

Accordingly, in the *Dokter* ruling, the Court held that that in cases of emergency the administration may adopt decisions without informing or hearing affected parties *during* the procedure, provided that, *after* the conclusion of the procedure, they are given the opportunity make their views known and contest the evidence on which those decisions were based.<sup>62</sup>

Postponing the moment for the exercise of the fundamental right to be heard from *before* to *after* the decision is adopted is considered by the Court to constitute a *proportionate* restriction to those rights. That restriction is deemed to be justified in the light of objectives of general interest (such as public health) and to leave the essence of the right to be heard untouched, as is generally required in the case law of EU courts and Article 52(1) of the Charter of Fundamental Rights.<sup>63</sup>

## 2. The *Malagutti-Vezinhet* case

The *Malagutti-Vezinhet* ruling gives us some indication of how much room there is to fulfil the duty of care in public health emergencies. The case emerged from the activation by a national authority of the Rapid Alert System (RAS) for product safety. The RAS, which was then enshrined in the General Product Safety Directive,<sup>64</sup> later came to be replaced in the domain of food safety by the Rapid Alert System for Food and Feed (RASFF).<sup>65</sup> The RASFF, similar to the Early Warning and Response System for health threats generally, facilitates quick exchanges of information between national authorities, with the intermediation of the Commission, in situations where there are immediate serious risks to human health.

The Commission received information from national authorities providing details about the network of undertakings – including *Malagutti-Vezinhet* – that were involved in the distribution of apples allegedly contaminated by an excessive level of pesticide residues. The Commission then circulated the information to the national contact point authorities within the RAS system, which in turn disseminated the information in their respective Member States. Consequently, *Malagutti-Vezinhet*'s trade suffered significant losses. The company therefore brought an action for damages against the Commission, arguing that the latter was required to check the information it had received from the national authorities “and to assess whether the

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facts and documents on which those measures are based and had expressed a view on those facts and documents, that authority could be prevented from acting promptly and effectively” (*Dokter*, supra, note 59, para 76).

<sup>62</sup> *Dokter*, supra, note 59, para 76. See T Binder et al. “Emergency! But What about Legal Protection in the EU?” (2018) 9(1) EJRR 99, at p 113 and A Keessen, *European Administrative Decisions: How the EU Regulates Products on the Internal Market* (Europa Law Publishing 2009) p 25.

<sup>63</sup> See for instance Joined Cases C-317/08, C-318/08, C-319/08 and C-320/08, *Alassini*, EU:C:2010:146, para 63; Case C-619/10, *Trade Agency*, EU:C:2012:531, para 55; and Case C-249/13, *Boudjlida*, EU:C:2014:2431, para 43.

<sup>64</sup> Council Directive 92/59/EEC of 29 June 1992 on general product safety. The Directive was replaced by Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, which is still in force.

<sup>65</sup> See Arts 50–52 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. On the mechanism, see M Weimer and E Vos, “The Role of the EU in Transnational Regulation of Food Safety: Extending Experimentalist Governance?” in J Zeitlin (ed), *Extending Experimentalist Governance: The European Union and Transnational Regulation* (Oxford University Press 2015) p 137.

risk concerned was genuine and whether it was immediate and serious, before forwarding those messages to the other Member States”.<sup>66</sup>

The Court of First Instance dismissed the application. It held that, even though the RASFF system’s legal provisions did entail an obligation on the part of the Commission to check “the conformity of the information received”, “the accuracy of the findings and analyses that led the national authorities to send that information does not have to be checked”.<sup>67</sup> Upon receiving alerts from national contact points, the Commission must only check if the evidence is “plausible”,<sup>68</sup> since “if it was necessary to wait until all the research was completed before adopting such measures, the precautionary principle would be rendered devoid of purpose”.<sup>69</sup>

While the ruling did not explicitly refer to the duty of care, the facts of the case, the arguments of *Malagutti-Vezinhet* can be construed in terms of that duty. If we assess the Court’s considerations against the requirements of the duty of care, as explained above, the Court’s reasoning raises fundamental questions. Is the urgent administrative action required in emergencies by definition incompatible with any serious attempt at carefully examining and assessing the facts based on which the emergency measures will be taken? Is it not possible to find any compromise between a prompt response to an emergency and a diligent collection and appraisal of the relevant evidence? The Court’s reasoning begs these questions and the judgments seem difficult to reconcile with the duty of care as presently understood.

### 3. Proportionality in times of emergency: bending, but not breaking with procedural demands

The case law of the EU’s courts tends to be rather lenient with the fulfilment of procedural requirements in cases of emergency. Granted, the urgency with which the administration is often called upon to address public health emergencies may be incompatible with the regular practices of observance of procedural rights requirements such as the right to be heard or the duty of care. In such cases, the immediate needs of the public interest must be balanced with the constitutional demand of respect for procedural rights. Nevertheless, what must be assessed critically is whether such balancing exercises should follow a one-size-fits-all model irrespective of the specific circumstances of each case. It is only once emergencies occur that the concrete nature and extent of their own dangers are revealed. It is therefore arguably only in the unique context of each emergency that one may establish what the required administrative measures will be, and the degree to which they may be adopted with disregarding individual rights.

Since the procedural guarantees of the right to be heard and the duty of care are protected as principles of EU constitutional law, their balancing with competing

<sup>66</sup> Case T-177/02, *Malagutti-Vezinhet*, para 30.

<sup>67</sup> *Malagutti-Vezinhet*, supra, note 66, para 52.

<sup>68</sup> *Malagutti-Vezinhet*, supra, note 66, para 53.

<sup>69</sup> *Malagutti-Vezinhet*, supra, note 66, para 54.



interest should be carried out carefully. Indeed, unlike legal rules, which can only be either applied or not applied, legal principles constitute “optimisation requirements”, which means they may be satisfied to varying degrees. Principles require an end to be realised to the highest degree that is factually and legally possible.<sup>70</sup> The status of rights of the right to be heard and the duty of care as EU constitutional principles therefore means that, *even in situations of emergency*, opportunities for participation in the decision-making process and a careful and impartial examination of each case must be ensured far as such is *factually and legally possible*.

In order to ensure that fundamental procedural rights such as the right to be heard and the administration’s duty of care are observed to the greatest degree possible, any limitations imposed to their exercise with a view to effectively address the emergency must be proportionate. Put differently, the balancing exercise between the need of an urgent decision and those two rights must not lead to those rights being more sacrificed than the factual circumstances of the emergency actually require. The balancing exercise must follow all of the key demands of the principle of proportionality, indeed, as Article 52 (1) of the Charter requires, in order for the requirement of observance of fundamental procedural rights to be legitimately lessened without being disregarded. It is compliance with proportionality, in short, that separates the lawful *bending* of that requirement from its unlawful *breaking*.

First, there is a requirement of *suitability* of the limitation to the right. The weakening of the demands posed by fundamental procedural rights must be *actually* fit for the purpose of adequately addressing the emergency. Second, proportionality requires that the more limited exercise of those rights is *necessary* to achieve the end that justifies that limitation. In other words, if the exercise of fundamental procedural rights must indeed be limited in order to address an emergency, then of all conceivable options to limit those rights, the solution must be chosen that constitutes the least invasive and restrictive means. Lastly, proportionality also places a demand to the limitation of fundamental rights that can be understood as *proportionality stricto sensu*. It requires an adequate relation between the benefits gained by fulfilling the end pursued by the limitation and the harm caused to the right in question that derive from that fulfilment. The requirement of proportionality *stricto sensu* will be failed if the harm produced upon the right to be heard or the duty of care exceeds the benefits of the limitation of their exercise in order to address the emergency.<sup>71</sup>

The demand that limitations to fundamental rights are proportionate is a recurring feature of various regimes of states of emergency. Article 15(1) of the European Convention on Human Rights (ECHR), for instance, provides that

“In time of war or other public emergency threatening the life of the nation any High Contracting Party may take measures derogating from its obligations under this Convention to the extent strictly required by the exigencies of the situation,

<sup>70</sup> R Alexy, *A Theory of Constitutional Rights* (Oxford University Press 2010) p 47.

<sup>71</sup> The various dimensions of proportionality explained here closely follow the analysis of A Barak, *Proportionality: Constitutional Rights and their Limitation* (Cambridge University Press 2012).

provided that such measures are not inconsistent with its other obligations under international law”.<sup>72</sup>

A similar provision that specifically addresses limitations to fundamental rights in cases of emergency, and requires such limitations to be only those “strictly required by the exigencies of the situation” does not exist in EU primary law. The limitation of fundamental rights such as the right to be heard and the administration’s duty of care must therefore be located in a different legal basis – namely, in Article 52(1) of the Charter of Fundamental Rights, and in the case law of EU courts on the role of proportionality in limiting fundamental rights.<sup>73</sup> One important difference that must be pointed out when comparing Article 52(1) of the Charter and Article 15(1) ECHR is that the former has a much broader scope, which means it governs limitations to fundamental rights in general, regardless of whether those limitations emerge in contexts of emergency, or indeed if the emergency is of a kind to “threaten the life of a nation” as is foreseen in the ECHR. This difference is important to note, since *not all* public health emergencies in the EU – in fact, very few of them – are actually of a scale that would risk compromising the entirety of the organised political and social life of a Member State of the EU as such. In the next section we zoom in on the EU rule of law demands as currently outlined for administrative action in major health emergencies.

#### IV. SAFEGUARDING THE RULE OF LAW IN MAJOR HEALTH EMERGENCIES

In the previous section the health emergencies were relatively mild. However, in case of a major health threat, the breaking/bending of the rule of law safeguards might be proportional in light of EU obligations to protect public health. In this section we analyse the Health Threats Decision in light of the previous findings that were based on constitutional emergency theory and EU administrative law so as to identify how the EU administrative rule of law would hold up when the proportionality of the response hypothetically shifted in case of a major emergency.

##### 1. Health Threats Decision

The overarching legal instrument for addressing a major EU health emergency is the Decision on Serious Cross-Border Threats to Health (“Health Threats Decision”) that was adopted in 2013 in response to the Swine Flu outbreak in 2009.<sup>74</sup> The objective of this Decision is to increase the role of the EU to respond to health security threats such as Zika, Ebola, bird flu, SARS, swine flu and the E-Coli outbreak.<sup>75</sup> Although

<sup>72</sup> On the provision and its interpretation, see O Gross and F Ní Aoláin, “From Discretion to Scrutiny: Revisiting the Application of the Margin of Appreciation Doctrine in the Context of Article 15 of the European Convention on Human Rights” (2001) 23(3) Human Rights Quarterly 625.

<sup>73</sup> For many, see T Marzal, “From Hercules to Pareto: Of bathos, proportionality, and EU law” (2017) 15(3) International Journal of Constitutional Law 621 and K Lenaerts, “Limits on Limitations: The Essence of Fundamental Rights in the EU” (2019) 20 German Law Journal 779.

<sup>74</sup> Decision No 1082/2013/EU, supra, note 11.

<sup>75</sup> “European Commission, Commission Staff Working Document, Health Security in the European Union and Internationally (SEC(2009)1622 Final) Brussels, 23/11/2009”.

the central authority for managing public health crises remains at Member State level, responses regarding the safeguarding of public health can affect the interests of other Member States, where they are based on different crises appraisals or inconsistent with measures taken in another Member State. The Health Threats Decision also aims at ensuring a proportionate and coordinated response to public health emergencies, particularly also where it relates to travel and trade restrictions.<sup>76</sup>

The Decision “bridge[s] the policy fields of health and security”,<sup>77</sup> and includes the EU’s role in infectious disease, but extends its legal scope to biochemical attacks, bioterrorism and hazards created as a result of climate change.<sup>78</sup> Hence, this Decision is an all-encompassing regulatory instrument, covering not only known, but also unknown health risks. Importantly the Decision connects or integrates horizontally the fields in public health where there are pre-existing administrative modes, systems and administrative processes for dealing with emergencies, such as in the area of food, the environment, chemicals and civil protection to name a few. Moreover, the Decision provides that coordinating structures:

“[S]hould, in exceptional circumstances, be available to the Member States and to the Commission when the threat is not covered by this Decision and where it is possible that public health measures taken to counter that threat are insufficient to ensure a high level of protection of human health.”<sup>79</sup>

This means that its emergency mechanisms could potentially be used in almost any type of public health threat. Implementing powers are conferred by the Decision to the Commission for, among other things, ad hoc monitoring of serious cross-border threats, defining the definitions of diseases and providing templates of information regarding preparedness and response.<sup>80</sup> Besides the possibility to adopt implementing acts in line with Regulation (EU) No 182/2011 on implementing and delegated powers, the Health Threats Decision also allows the Commission, where there are imperative grounds of urgency, to adopt immediately applicable implementing acts, where this is duly justified in light of the severity or the novelty of the cross-border threat to health, or the speed with which a disease spreads.<sup>81</sup> Furthermore, in exceptional emergency situations, both a Member State or the Commission can request the Health Security Committee to coordinate the response,<sup>82</sup> in cases where

<sup>76</sup> European Commission Staff Document, “European Commission Staff Document, Regulatory Process for the Authorization of Antiviral Medicines and Vaccines in the Protection against Pandemic Influenza H1N1 2009, Accompanying Document to the Communication to the Commission to the Council, the European Parliament and the European Economic and Social Committee and the Committee of Regions, Pandemic Influenza H1N1 2009 (COM(2009) 481-SEC(2009)119 Final)”.

<sup>77</sup> Commission Proposal, “Commission Proposal for a Decision of the European Parliament and of the Council on Serious Cross-Border Threats to Health Brussels (COM (2011)866 Final)”.

<sup>78</sup> Decision No 1082/2013/EU, *supra*, note 11, at para 8.

<sup>79</sup> *ibid*, at para 9.

<sup>80</sup> Art 18 Health Threats Decision; *ibid*, 30. However, Art 5(4) of Regulation (EU) No 182/2011, particularly where it concerns issue of human health, limits the power of the Commission where the Committee on Serious Cross-Border Threats has not delivered an opinion.

<sup>81</sup> Art 12 Health Threats Decision, para 31, and see Art 8 Regulation (EU) No 182/2011.

<sup>82</sup> Art 11 Health Threats Decision.

previous measures are deemed insufficient to maintain a high level of health in the Union.<sup>83</sup>

The Commission has the power under this Decision to determine that there is an emergency when it considers there is a threat of a pandemic of human influenza or for other public health threats. Before recognising a situation of public health emergency at Union level, the Commission should liaise with the WHO, so that the WHO is informed on the Commission's intention to determine that there is an emergency and in order to coordinate if the WHO shares the analysis of the emergency situation. The Commission can also declare an emergency when the Director of the WHO has not yet declared a Public Health Emergency of International Concern,<sup>84</sup> and where this threat endangers human health within the Union,<sup>85</sup> or in case there are medical needs, such as pandemic vaccines or other medical needs are authorised within the Union, and this authorisation is needed to safeguard the health of European citizens.<sup>86</sup>

The legal effects of the recognition of a health emergency<sup>87</sup> is that the emergency procedures for the approval of medical countermeasures can be used and that vaccines or other medical countermeasures can be approved on less than usual, or missing, clinical data available for assessing the safety of medicines.<sup>88</sup> For example the approval of eg Pandemrix, a vaccine against Swine flu, that was given to about 30 million Europeans, was done through the use of a special emergency procedure,<sup>89</sup> that ensured the speed of the approval process, but left less time to consider the risks and benefits of this particular vaccine.<sup>90</sup> Pandemrix was found to be associated with an increased risk for narcolepsy, which in turn had impact on public trust in vaccination on the whole.<sup>91</sup>

The Commission can also terminate the recognition of a human health emergency by implementing act, as soon as the situation no longer warrants the emergency state as outlined in Article 12 of the Health Threats Decision.<sup>92</sup> The termination of the recognition does not affect the marketing authorisation of medical countermeasures

<sup>83</sup> Art 2(4) Health Threats Decision.

<sup>84</sup> Art 12(1)(a) Health Threats Decision.

<sup>85</sup> Art 12(1)(b)(i) Health Threats Decision.

<sup>86</sup> Art 12(1)(b)(ii) Health Threats Decision.

<sup>87</sup> Art 13 Health Threats Decision.

<sup>88</sup> Art 2 of Regulation (EC) No 507/2006; Art 21 of Regulation (EC) No 1234/2008.

<sup>89</sup> This was when the medicinal legislation was still dependent on a WHO declaration of emergency (The Health Threats Decision currently provides the possibility for declaring an emergency at EU level) "Commission Staff Working Document, Regulatory Process for the Authorisation of Antiviral Medicines and Vaccines in the Protection against Pandemic Influenza (H1N1) 2009 Accompanying Document to the Communication from the Commission to the Council, the European Parliament, and the European Economic and Social Committee and Committee of the Regions, Pandemic Influenza A (H1N1) 2009 (COM(2009) 481 Final)".

<sup>90</sup> I Persson et al, "Risks of Neurological and Immune-Related Diseases, Including Narcolepsy, after Vaccination with Pandemrix: A Population- and Registry-Based Cohort Study with over 2 Years of Follow-up, January 2014" (2014) 1 *Journal of Internal Medicine*; T Verstraeten et al, "Pandemrix™ and Narcolepsy: A Critical Appraisal of the Observational Studies" (2016) 12 *Human Vaccines & Immunotherapeutics* 187; A Bangerter et al, "Longitudinal Investigation of Public Trust in Institutions Relative to the 2009 H1N1 Pandemic in Switzerland" (2012) 7 *PLoS ONE* e49806.

<sup>91</sup> Persson et al, *supra*, note 90.

<sup>92</sup> Art 14 Health Threats Decision.

that have been approved for the emergency. On the whole the Decision interacts with risk regulation and emergency structures in other contexts such as food or bio-chemical threats. At the same time, the Decision acts as a gap-filler for unforeseen emergency situations, which generally brings health emergencies within a legal structure, whereas before these might be coordinated in a more extra-legal ad hoc manner. Furthermore, the Health Threats Decision expands EU activities. The Health Security Committee, created under this Decision, represents the Member States' governments at a higher level than the usual committees, and can therefore take decisions quicker, outside of the committee structures.<sup>93</sup> This Committee since its informal inception in 2001 and its formalisation in 2013 to currently, has expanded in a number of working groups, on eg health sector preparedness for (bio) terrorism, emergency planning etc.

## 2. Proportionality and the rights of defence in the case of major health threats

In the following section we consider the implications of the rule of law in emergencies that follows from the Courts' practice in case of a major emergency as foreseen by the Health Threats Decision. Arguably the nature of the emergency might change the proportionality of the response that is to be expected and the impact in terms of bending or breaking the rule of law safeguards.

In the emergency provisions of the Health Threats Decision there are no provisions that provide for a fair hearing or the duty of care. However, as was highlighted above, these are principles of EU law that apply regardless of whether they are codified in the legislation applicable in case of emergencies. Yet the application of these principles and the possibility for upholding the administrative rule of law generally is, in case of a major health threat, highly dependent on the type of emergency and counter measures that are needed, and the particular applicable legal regime (food, infectious disease, bioterrorism (security) etc).

With regard to a standard of care, the Health Threats Decision clearly outlines that all assessment of risks needs to be based on a coordinated organisation of scientific expertise, that is "appropriate" and in accordance with principles of "excellence, independence, impartiality and transparency".<sup>94</sup> One of the central aims of the Decision is to coordinate those situations where Member States' risk assessments might diverge, so as to ensure a proportional response that does not impede more than necessary other interests such as trade and travel.<sup>95</sup> Furthermore, the Decision aims to prevent inconsistent or unclear communication to the public and health professionals about the nature and the severity of the health risk.<sup>96</sup> The risk assessment is largely carried out by the relevant agencies (EMA, EFSA, ECDC) in accordance with their respective powers. However, if the risk assessment were to fall outside of the competencies of these agencies, the Decision foresees the possibility of "ad hoc risk assessment" by the Commission.<sup>97</sup> The procedures for this risk

<sup>93</sup> Art 17 Health Threats Decision.

<sup>94</sup> Decision No 1082/2013/EU, supra, note 11, Recital 17.

<sup>95</sup> *ibid*, Recital 21.

<sup>96</sup> *ibid*, Recital 22.

<sup>97</sup> Art 10(2) Health Threats Decision.

assessment would have to be established through an implementing act based on Article 5 of Regulation (EU) No 182/2011.

The Health Threats Decision and the related pharma regulations, allow – once an emergency is declared – the duty of care for the approval of medicines to be lowered, in that the timeline of the approval process is shortened and less medical evidence for the risk-benefit analyses will have to be provided by the producer of the medicine. In this process, although the company making the application is heard, patients do not play an explicit role. Furthermore, ex-post accountability through eg product liability is usually limited at Member State level in pre-purchase contracts for medicinal counter measures.<sup>98</sup> While the declaration of an emergency through the procedure in the Decision has a limited *legal* effect, such a declaration can also have an important political effect, as it can embolden Member States to use their own emergency powers.

The declaration of an emergency is a powerful right, which may have legal implications beyond the approval of medicines. The emergency can be immediately implementable (up to six months), which puts pressure on the Committee process, which may impact the duty of care.<sup>99</sup> Importantly, also the end of the recognition of the emergency is to be initiated by the Commission, using the same committee structure.<sup>100</sup> This means that neither the Court nor the Parliament is involved in the beginning or the end of the emergency situation. There is also no – not even in any of the secondary legal regimes that are connected through the Health Threats Decision – explicit guidance on proportionality. The implications of the declaration of a health emergency (beyond the activation of the pharmaceutical legal regime) would have to be part of a proportionality consideration, particularly as this could jumpstart response measures under Member State competence that can have more far-reaching impact on fundamental rights, such as the right to liberty or physical integrity.

For, although Member States have retained full powers to act in cases of serious health threats, the decisions that can be made under the Health Threats Decision can have serious implications for the fundamental rights of EU citizens or third country nationals.<sup>101</sup> A decision to instigate contact tracing, passenger screening, or publishing public advisories on public health measures, such as school closures and quarantines are all emergency responses that may immediately infringe on individual freedoms. For example, contact tracing allows public health authorities to receive identification and contact information of persons that have been in contact with someone who was carrying a pathogen.<sup>102</sup> Contact tracing is coordinated by the EU through a (RAS) Early Warning and Response Mechanism. This means that people's sensitive medical information is transferred across the borders to other public health authorities, such as the confirmed or suspected persons carrying a disease. The processing of personal

<sup>98</sup> M Turner, "Vaccine Procurement during an Influenza Pandemic and the Role of Advance Purchase Agreements: Lessons from 2009-H1N1" (2016) 11 *Global Public Health* 322.

<sup>99</sup> Art 8 Regulation (EU) No 182/2011.

<sup>100</sup> Art 14; Art 18 Health Threats Decision.

<sup>101</sup> When the EU identifies public health risks, this is a central reason for denying a person entry to EU under the Dublin procedures.

<sup>102</sup> P Dąbrowska-Kłosińska, "Tracing Individuals under the EU Regime on Serious, Cross-Border Health Threats: An Appraisal of the System of Personal Data Protection" (2017) 8 *EJRR* 700.



data on medical history and contacts should be done in accordance with data protection legislation; however, this legislation allows for public health exceptions.<sup>103</sup> As to the duty of care, the Decision does not provide for individual possibilities to prevent information being transferred through the EWRS, or in the context of the Health Security Commission.

### 3. Between breaking and bending: the case for proportionality in major health emergencies

The EU's constitutional framework does not give a clear legal guideline as to what general principles would apply and what would constitute a proportional response with respect to the institutions of the EU and also with respect to the Member States as they coordinate their response in relation to the EU systems for public health and emergency responses. The most relevant starting point to critically assess the solutions are as outlined by the Court, where it addressed how administrative duties such as the right to be heard and the duty of care – which are required by the rule of law itself – must be reconciled with the pressing needs of public health emergencies. In that light, both the *Dokter* and the *Malagutti-Vezinhet* models of reconciling those ends can be seen as incomplete. Not all emergencies are born equal. Not all of them will be of a nature that would necessarily justify immediately excluding affected parties from any hearing, no matter how summary. Some situations of emergency are compatible with a minimal fulfilment of rights of the defence, by allowing their exercise in a simplified, abridged form. Under EU constitutional law, the mere presence of a public health emergency (or an emergency of any other kind) cannot mean an automatic blank cheque to bypass fundamental procedural rights.

The solution in *Dokter* expands the wide discretion that public administration already typically enjoys in cases of emergency by making the very observance of the right to be heard in the course of an administrative procedure a discretionary choice. Yet, procedural requirements are all the more important where the administration has a large margin of discretion. Under EU law, and under the law of many Member States,<sup>104</sup> courts cannot review the merits of administrative decision making, and the substance of discretionary measures in particular is beyond their control. However, what courts can and should do is to “verify whether the relevant procedural rules have been complied with”.<sup>105</sup>

Generalising the *Dokter* ruling to all emergencies would mean giving the administration a blanket permission to bypass and *break with* constitutional demands of respect for procedural requirements precisely where their observance is needed the most. In the *Dokter* ruling, the Court of Justice explicitly recognised that not even situations of (public health) emergencies justify doing away with *all* constitutional restraints. In adopting urgent measures, the CJEU held, “the competent authority may adopt those measures only in compliance with the general principles of Community law, including in particular the principle of proportionality and

<sup>103</sup> Art 16 Health Threats Decision, and see *ibid*.

<sup>104</sup> Fioritto, *supra*, note 12, p 115.

<sup>105</sup> T-75/06, *Bayer CropScience*, EU:T:2008:317 paras 81–84; T-35/01, *Shanghai Teraoka Electronic*, EU:T:2004:317, paras 48–49.

fundamental rights”.<sup>106</sup> Hence the interpretation of the rule of law (the right to be heard) in the *Dokter case*, if it were to be generalised, would render this procedural guarantee toothless even in situations where it could be exercised summarily.

Even setting aside considerations of individual procedural protection,<sup>107</sup> a summary exchange could constitute the last chance for individuals to point out serious and manifest inaccuracies in the evidence that the administration will use. A solution of this kind could serve as a last line of defence to promote the function of procedural rights, of avoiding the misguided or misinformed exercise of power. Where possible, even a single public hearing for patients or public health groups, or a quick notification to the manufacturer or trader that her product will probably need to be recalled from the market, could serve procedural rights. It would minimise the impact of a surprise decision and give affected parties an opportunity to plan accordingly for the impending measure and, to those who are willing to cooperate with the administration, the opportunity to do so. Lastly, notifying affected parties prior to the urgent measure can also be combined with the *Dokter* solution, as the notification would allow them better to prepare themselves for the *ex post* hearing.

The *Malagutti-Venzinhet* ruling shows how Rapid Alert systems can also be problematic from the point of view of the duty of care. In the name of the precautionary principle and of risks to public health, the Court of First Instance exempted the EU administration from checking the accuracy of the information it receives. In doing so, it effectively absolved EU authorities from the duty to observe even a minimal degree of care. Not requiring an authority to fulfil the duty of care at all is a solution that might not necessarily be justified in light of proportionality. It can fail the requirement of necessity, of finding the least restrictive possible means of protecting the duty of care, since that duty is by default waived from the administration. It can also fail the test of proportionality *stricto sensu* – of ensuring that the harm to the duty of care does not exceed the benefits to the purpose addressed – given that the administration cannot tell in advance – before taking the decision *not* to carefully gather and consider all relevant facts – whether there actually are factual elements that it needs to be aware of before adopting potentially very damaging urgent measures. Not requiring the administration to at least *try* to comply with the duty of care is in essence the same as a free pass to ignore the relevant facts it must grapple with when addressing an emergency.

This is not to say that there may be not some emergencies where it will be impossible to perform a proper check of the evidence supplied by national administrative actors without avoiding imminent risks from having more serious consequences. And indeed, in the pharmaceutical regulation in conjunction with the Health Threats Decisions we do find a carefully considered administrative procedure for shortening the approval process for pandemic medicines in attempting to preserve the duty of care in the form of a risk-benefits analysis. However, this does not seem to have been the case in *Malagutti-Vezinhet*, where French authorities were quickly able to establish that the product at stake conformed with limits on residue pesticides. From

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<sup>106</sup> *Dokter*, supra, note 59, para 71.

<sup>107</sup> This is the point of view emphasised by Binder et al, supra, note 62.

reading the facts of the case, it seems that it might have been possible for the Commission to have gathered this additional evidence and to seek to restrict the scope of the alert. Moreover, the Court's stance, holding that "plausible" alerts should suffice, and absolving the Commission from any responsibility in checking the accuracy of evidence, seems irreconcilable with the position currently expressed by the Court of Justice today that even urgent measures adopted to address emergencies must be "based on a risk assessment as complete as possible in the particular circumstances of an individual case".<sup>108</sup>

In sum, if one considers the various tests of the principle of proportionality, it appears that the *Dokter* ruling bent the requirement of the right to be heard in a way that may have been *necessary* in the case, but which would lead to a breaking of that requirement in other cases and under different factual circumstances. As for the *Malagutti-Vezinhet* ruling, it is irreconcilable with the duty of care, and must be seen as a solution that breaks that very important rule of law requirement. The implications of these two solutions for the fulfilment of rule of law demands in emergencies are significant – all the more so in the case of major health emergencies. Indeed, failure to allow any kind of exchange of views between administration and those negatively affected by its urgent measures may constitute a violation of their right to be heard on a mass scale. There is of course the evident counter-argument that it is *precisely* because major health threats may involve an extremely high number of affected private parties, that it would be entirely impractical for the administration to be responsive to their concerns. Yet, again, the nature of the right to be heard as a legal principle does not mean that a hearing must be offered to each and every affected party in an extensive manner, but rather that those parties have, *where and to the extent possible*, the opportunity to inform public authorities of interests they must take into account before taking urgent decisions. Larger-scale public health crises may not be compatible with individual hearings and sophisticated (time-consuming) forms of consultation of interested parties. However, it is at the same time not unthinkable that an emergency can be effectively addressed while still notifying all affected private parties of the measures that are about to be taken in their respect and giving them a timeframe – even if a short one – to point out manifest mistakes that the administration is about to make or that there are important interests it must know about before actually enforcing those urgent measures. What constitutes the greatest degree factually and legally possible to which a principle can be observed can only be determined in light of every concrete situation.

For the very same reasons, if the quite weak approach of EU case law to the duty of care is to be followed in the context of major health threats, authorities in the EU risk taking irrational and grossly uninformed decisions on a systemic scale. An approach to information-gathering and use similar to that in *Malagutti-Vezinhet* could have quite disastrous implications if generalised to much larger crises, as it would exempt public authorities from even a minimal degree of careful analysis and collection of facts before taking fundamental decisions to quell public health emergencies.

<sup>108</sup> Joined Cases C-58/10 to C-68/10, *Monsanto*, EU:C:2011:553, para 77.

## V. THE EU EMERGENCY ADMINISTRATION IN PUBLIC HEALTH

In this last section we consider our findings regarding the rule of law and the state of emergency in the field of public health more generally in terms of breaking and bending the administrative rule of law. We outline that the scope for breaking or bending the rule of law in case of an emergency is broad, particularly when it comes to participatory procedures. In this article we first outlined the general considerations for breaking or bending constitutional limits of the rule of law in cases of emergencies. Second, we zoomed in on the EU administrative legal space for safeguarding or breaking and bending rule of law provisions. Particularly we looked at two legal cases in the field of public health, which showed an extraordinary room for breaking the rule of law provisions in case of an emergency. We then outlined the regulatory scope of the relatively recent legislation regarding major health threats, and concluded that the potential impact of emergency decisions is amplified given the scope of the Decision and the types of threats that are covered by it. At the same time, in the case of major health threats the decision does bring the EU emergency response within a legal frame.

EU powers tend to only partly overlap with the typical characteristics of emergency powers generally foreseen in national administrative laws identified by scholars such as Fioritto.<sup>109</sup> The administrative emergency powers provided for by EU law have an unusually broad scope in comparison to other administrative powers, both in respect of the uncategorised and unforeseeable types of urgent measures that can be adopted on their basis, and in respect of their ill-defined remit of application. The main – sometimes sole – condition for their exercise is the presence of an immediate need to address a real or imminent danger for a public interest. What appears to be distinctive in EU administrative law is that, rather than following the more common solution of allowing for temporary, isolated derogations of legal requirements that would usually apply to the relevant administrative actor, the legislative framework and case law on administrative emergencies in the EU overwhelmingly enshrine such derogations as part and parcel and a normal aspect of the EU's response to public health emergencies. For instance, as we have seen in the Health Threats Decision, an immediately applicable implementing act can remain in place for six months. This strongly resonates with how Agamben described the modern state of exception as attempts to include exceptionality into the legal order.<sup>110</sup>

In terms of administrative EU rule of law in an emergency, the *Dokter* and *Malagutti-Venzhinet* cases illustrate the challenges that public administrations face when they are simultaneously confronted with the need to exercise their emergency powers and the rule of law's requirements pertaining to the observance of administrative process rights. Both judgments show how difficult it can be to find an appropriate and proportional balance between the two demands. Yet, they also contain solutions that should not be held to be immediately extensible to all cases of administrative emergency. The CJEU sets a low bar for public administration in its duty to uphold

<sup>109</sup> Fioritto, *supra*, note 12, p 96 ff.

<sup>110</sup> G Agamben, *State of Exception* (University of Chicago Press 2005) pp 25–26.

the rights of the defence in public health emergencies, which can be concluded from our analyses of the general rule of law principles as they are applied in these two singular cases. Indeed, insofar as we can derive general conclusions from these cases, the court allows for the administration to break with upholding the rights of defence, when it deems it appropriate in light of the immediacy of the emergency.

Nevertheless, we must emphasise that the CJEU's approach in *Dokter* and *Malagutti-Vezinhet* was in no way inevitable. Even in cases of emergency, we can conceive of some ways to observe the rights of the defence without the ambition to give them the fullest possible protection that they would enjoy beyond emergencies, in situations of normalcy. It is worth pointing out that the EU legislature itself has on occasion established similarly abbreviated forms of procedural participation. The original RAS (food) established that, "as soon as a serious and immediate risk is detected, the national authority shall consult, *insofar as possible and appropriate*, the producer or distributor of the product concerned" (emphasis added). The provision made clear that this consultation fulfilled an important purpose of informed decision-making: the affected parties' "point of view and the details which they supply may be useful both to the administrations of the Member States and to the Commission in determining what action should be taken".<sup>111</sup> This solution, which has merits of flexibility, of individual protection, and of promoting the accuracy of informational exchanges, has disappeared from the current regime of the RASFF in the general food safety regulation.

Public health emergencies may in many cases be (perhaps more) effectively addressed when allowing for a hearing. This will arguably be the case in the urgent administrative procedures in food safety set out above; the Commission, in consultation with EFSA, holds the power to confirm, amend, revoke, or extend provisional urgent measures *that were already taken* at EU or national level. Given that those measures remain in force during the confirmation procedure, it is difficult to argue that the emergency will cease to be adequately addressed if the Commission carries out a hearing while deciding on their continuity.

However, particularly in the case of major health threats, where a full hearing of those affected (which could potentially be millions of citizens) is unfeasible, other forms of participation, however simplified and abridged, could be deployed before urgent measures are taken. For instance, the effectiveness of administrative action may not necessarily be compromised if even a summary exchange of views is facilitated between authorities and affected parties before the final decision. Currently, the Health Threats Decision does demand that the Commission inform the Member States of a risk assessment, before the risk assessment is published.

On the whole, the EU's constitutional framework guiding administrative practice for public health emergencies is rather scattered across secondary legislation and depends on the nature of the emergency and the specific policy area. The current guidance by the court is limited and does not seem well prepared for a major health emergency. Particularly in case of major health threats, the proportionality and the adherence to the rule of law by the EU administration may be seen as protecting the public health of the EU legal system as a whole. As we have seen in the case of the Influenza

<sup>111</sup> Annex to Council Directive 92/59/EEC of 29 June 1992 (previous general product safety regulation), point 3.

AH1N1, an overreach or disproportional response of public authorities will have an impact on public trust in public health authorities that will impact the ability to manage future emergencies. The principles of administrative law, such as the rights of the defence, give a good guideline as to how to ensure to the fullest extent possible the adherence to the rule of law. These principles will make a difference for judging the proportionality of the response and whether or not public authorities bent or broke the EU rule of law in an emergency.