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# Precautionary Principle and Impact Assessment: The Case of School Closures during the Pandemic in Ireland

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## Abstract

The development of the precautionary principle by the EU Courts has often been interpreted by scholars as inconsistent with another trend in EU risk regulation: one that is evidence-based and relies on impact assessment. This article argues that the two trends – precaution and regulatory impact assessment – are not mutually exclusive. Together they may, in fact, act as a procedural safeguard against discretionary decisions that have an impact on fundamental rights, especially under conditions of epistemic uncertainty. The article illustrates this claim by looking at the decisions to close schools in Ireland during the pandemic.

**Keywords:** human rights; impact assessment; pandemic; precautionary principle

## I. Introduction

In a “risk society”<sup>1</sup> – some would even say in a “multi-risk world”<sup>2</sup> – one elementary question for risk managers is how to respond to risks when confronted with insufficient information to make well-informed decisions – that is, when facing Knightian, epistemic, uncertainty.<sup>3</sup> The precautionary principle provides an appealing and relatively simple regulatory strategy: when in doubt, be cautious. Thus, when faced with uncertainty, a decision-maker may take *ex ante* regulatory measures aimed at avoiding a potential harm.<sup>4</sup>

As a general principle of EU law and a key tenet of EU risk regulation, the precautionary principle has been developed by the EU Courts.<sup>5</sup> This development has been interpreted by

<sup>1</sup> U Beck, *Risk Society: Towards a New Modernity* (Sage Publications 1992).

<sup>2</sup> JB Wiener, “Precaution in a Multi-Risk World” in DJ Paustenbach (ed), *Human and Ecological Risk Assessment: Theory and Practice* (John Wiley & Sons, Inc 2002).

<sup>3</sup> F Knight, *Risk, Uncertainty and Profit* (Houghton Mifflin 1921). For recent accounts of decision-making under epistemic uncertainty, see J Kay and M King, *Radical Uncertainty: Decision-Making for an Unknowable Future* (The Bridge Street Press 2020); CR Sunstein, *Averting Catastrophe: Decision Theory for COVID-19, Climate Change, and Potential Disasters of All Kinds* (New York University Press 2021).

<sup>4</sup> The literature on the precautionary principle is vast. A small sample includes Wiener (n 3); JB Wiener and MD Rogers, “Comparing Precaution in the United States and Europe” (2002) 5 *Journal of Risk Research* 317; CR Sunstein, “Beyond the Precautionary Principle” (2003) 151 *University of Pennsylvania Law Review* 1003; G Majone, “The Precautionary Principle and Its Policy Implications” (2002) 40 *Journal of Common Market Studies* 89; J Morris (ed), *Rethinking Risk and the Precautionary Principle* (Butterworth-Heinemann 2000); O Renn, *Risk Governance: Coping with Uncertainty in a Complex World* (Earthscan 2008); C Hood, H Rothstein and R Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford University Press 2001).

<sup>5</sup> Majone (n 5); RE Löfstedt, “The Swing of the Regulatory Pendulum in Europe: From Precautionary Principle to (Regulatory) Impact Analysis” (2004) 28 *Journal of Risk and Uncertainty* 237; K De Smedt and E Vos, “The

scholars as inconsistent with another trend in EU risk regulation: one that is evidence-based and relies on impact assessment.<sup>6</sup> This article argues that the two trends – precaution and regulatory impact assessments – are not mutually exclusive. Together they may, in fact, act as a procedural safeguard against discretionary decisions that have an impact on fundamental rights, especially under conditions of epistemic uncertainty. The article illustrates this claim by looking at the decisions to close schools in Ireland during the pandemic.

From a legal perspective, impact assessment is a decision-making tool that falls within the realm of administrative law.<sup>7</sup> As a procedure, it takes the form of structured reasoning, based on the proportionality principle. It requires the quantification of the impacts of regulatory interventions (or non-interventions), including their costs and benefits.<sup>8</sup> It is best understood as an aid to policymaking<sup>9</sup> and covers the whole policy cycle<sup>10</sup> – that is, it helps to identify policy problems and their underlying causes, assess whether intervention is needed, review different regulatory options, including their advantages and disadvantages, and deliver solutions that contribute to better results in terms of legitimacy, accountability, and competitiveness.<sup>11</sup> Thus, impact assessment is a pragmatic tool, in the sense that its *ex ante* formulation is subsequently reviewed in light of its *ex post* application.<sup>12</sup>

The Irish regulatory framework requires governmental departments and offices to undertake a regulatory impact analysis for all proposals for primary legislation, significant statutory instruments, EU directives and significant EU regulations, and for proposals from Policy Review Groups.<sup>13</sup> One noticeable exception from this requirement is, however, emergency legislation. The 2009 Revised RIA Guidelines specifies that where emergency legislation is required (such as to stop the spread of a disease), there is no requirement to carry out a regulatory impact analysis.<sup>14</sup> The Health (Preservation and Protection and

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Application of the Precautionary Principle in the EU” in HA Mieg (ed), *The Responsibility of Science*, vol 57 (Springer International Publishing 2022); A Alemanno, “The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty” in L Cuocolo and L Lupária (eds), *Valori costituzionali e nuove politiche del diritto: scritti raccolti in occasione del decennale della rivista Cahiers Européens* (Halley 2007).

<sup>6</sup> European Commission, “Commission Staff Working Document: Better Regulation Guidelines” (European Commission 2021) Guidelines SWD 305. On the contradiction, see A Alemanno, “Risk vs Hazard and the Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt” (2011) 2 *European Journal of Risk Regulation* 169; Löfstedt (n 6).

<sup>7</sup> For an overview of regulatory impact assessment, see CA Dunlop and CM Radaelli (eds), *Handbook of Regulatory Impact Assessment* (Edward Elgar Publishing 2016).

<sup>8</sup> Department of the Taoiseach, “Regulating Better: A Government White Paper Setting out Six Principles of Better Regulation” (2004) White Paper; European Commission (n 7) 7; OECD, *Better Regulation in Europe: Ireland 2010* (OECD 2010).

<sup>9</sup> Department of the Taoiseach, “Revised RIA Guidelines: How to Conduct a Regulatory Impact Analysis” (2009) 4; European Commission (n 7) 30.

<sup>10</sup> The EC 2021 Guidelines requires impact assessments to answer seven questions: 1. What is the problem and why is it a problem? 2. Why should the EU act? 3. What should be achieved? 4. What are the options for achieving the objectives? 5. What are their economic, social and environmental impacts and who will be affected? 6. How do the options compare (effectiveness, efficiency and coherence)? 7. How will monitoring and subsequent evaluation be organised? European Commission (n 7) 31–2.

<sup>11</sup> Department of the Taoiseach (n 10) 4. Some have also suggested that better results should be understood in terms of societal well-being – that is, improving societal net benefits at minimum cost and/or more protection. See for instance JB Wiener, “Better Regulation in Europe” (2006) 59 *Current Legal Problems* 447, 460.

<sup>12</sup> Department of the Taoiseach (n 9); OECD (n 9) 109. Note that this pragmatic approach is sometimes referred to as the “learning from experience approach”. The European Commission has adopted this expression when referring to the process of learning from the “experience of implementation and applying EU rules on the ground”. Commensurate to this approach is the “evaluate first” principle, which requires policymakers to evaluate the current regulatory framework before revising legislation. European Commission (n 7) 6.

<sup>13</sup> Department of the Taoiseach (n 10).

<sup>14</sup> Other exceptions include the Finance Bill, security, and some criminal legislation. *Ibid.*, 11.

Other Emergency Measures in the Public Interest) Act 2020 adopted during the Covid-19 pandemic falls within this exception.<sup>15</sup> Therefore, it was expected that many Covid-19 regulatory decisions would be made absent an impact assessment.

The article will demonstrate that in the context of school closure, the governmental decisions were based on different versions of the precautionary principle, even though this principle was never mentioned explicitly. Notwithstanding this reliance, some decisions were also supported by an impact assessment of some forms; but not all. The question, then, is which of these decisions had the least negative impacts on the right to education of children?

This article proceeds as follows. The second part provides an overview of the literature on the precautionary principle and one of its versions, the maximin rule. The third part reviews the governmental decisions relating to school closures in Ireland during the pandemic and identifies the version of the precautionary principle, upon which they were based. To the extent that these findings rerun the debate between precaution and impact assessment, the fourth part analyses the decisions of the General Court in *BASF v Commission*<sup>16</sup> and *Bayer CropScience v Commission*.<sup>17</sup> The fifth part explains what we learn from this study and what prospects it has for a more evidence-based approach to precaution when fundamental rights are at stake.

Note that the following analysis is normative in its scope and based on the evidence available at the time of the decision-making process. Thus, the paper will exclude considerations relating to societal values and risk perception notwithstanding their importance in risk management.<sup>18</sup>

## II. What is the precautionary principle?

Precautionary regulation has a long history; the principle was initially rooted in German environmental policy in the 1970s before being internationalised thereafter.<sup>19</sup> For instance, the principle features in the 1982 World Charter for Nature, the 1992 Rio Declaration on Environment and Development, the 1992 UN Framework Convention on Climate Change and its subsidiary, the Kyoto Protocol. The principle is now ubiquitous and a general principle of international law.<sup>20</sup> Within the European Union, the principle was articulated by the European Commission in a 2000 communication and currently features in Article 191 of the Treaty on the Functioning of the EU (TFEU).<sup>21</sup> While most of its reference in international documents relates to environmental law and policy, its scope is much wider in practice; it is an overarching principle in risk regulation.<sup>22</sup>

<sup>15</sup> Act No 1 of 2020, <<https://www.irishstatutebook.ie/eli/2020/act/1/enacted/en/html>> (last accessed 11 March 2024).

<sup>16</sup> Case T-584/13 *BASF Agro and Others v Commission*, EUCLI:EU:T:2018:279.

<sup>17</sup> Case T-429/13 *Bayer CropScience v Commission*, ECLI:EU:T:2018:280.

<sup>18</sup> On the importance of relevance claims in addition to normative and evidence claims, see Renn (n 5) 4.

<sup>19</sup> The principle is often associated with the German notion of Vorsorgeprinzip. For helpful discussions of the evolution of the precautionary principle, see J Morris, "Defining the Precautionary Principle" in J Morris (ed), *Rethinking Risk and the Precautionary Principle* (Butterworth-Heinemann 2000); Commission of the European Communities, "Communication from the Commission on the Precautionary Principle" (European Commission 2000) COM (2000) 1 final.

<sup>20</sup> Commission of the European Communities (n 20) 10.

<sup>21</sup> Commission of the European Communities (n 20).

<sup>22</sup> C Hood, H Rothstein and R Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford University Press 2004); Wiener and Rogers (n 5); Commission of the European Communities (n 20).

Notwithstanding its international fame, there is a lack of consensus as to the meaning of the precautionary principle(s).<sup>23</sup> Overall, the principle is best understood as a continuum of principles, varying in terms of their degree of precaution.<sup>24</sup> Wiener identifies three versions that best reflect this spectrum.<sup>25</sup> At one extreme, the absence of certainty of harm should not constitute a reason for refusing to regulate an action that might be potentially harmful. Thus, these weak versions call for action whenever there is a potential risk to human health or the environment, even though the supporting evidence is inconclusive.<sup>26</sup> At the other extreme, strong versions of the principle, sometimes referred to as ultraconservative,<sup>27</sup> require banning any potentially risky activity until and unless there is certainty that these activities will cause no harm. What these latter versions operate is a shift of burden of proof from regulators to those engaged in potentially risky activities.<sup>28</sup> Finally, in between these two narratives, you have a middle ground, which justifies (as opposed to call for action) regulatory intervention(s) when faced with uncertain risks.<sup>29</sup>

Despite their differences in degree, all of these versions share a common denominator: for the principle to apply, the situation must be one of uncertainty, in which there is an absence of probability information or a degree of distrust in the veracity of information. Thus, the common perception that mere risks, which can be predicted based on probability, warrant an application of the precautionary principle is misleading.<sup>30</sup> For risks to trigger the application of the principle, these risks must be uncertain.<sup>31</sup>

As mentioned above, the European Commission issued a communication on the precautionary principle in 2000.<sup>32</sup> While it clarifies the components of the principal, it falls short of providing a clear definition.<sup>33</sup> Thus, it is not entirely clear to which version(s) the communication subscribes.<sup>34</sup> At times, a middle ground version of the principle is found in the caselaw of the European Courts.<sup>35</sup> At other times, a strong version of the principle is

<sup>23</sup> For helpful discussions on the precautionary principle, see Sunstein, “Beyond the Precautionary Principle” (n 5); Stephen M Gardiner, “A Core Precautionary Principle” (2006) 14 *Journal of Political Philosophy* 33; CR Sunstein, “Maximin” (2020) 37 *Yale Journal on Regulation* 940; A Vermeule, “Precautionary Principles in Constitutional Law” (2012) 4 *Journal of Legal Analysis* 181.

<sup>24</sup> Wiener notes that 19 different versions of the principle have been previously recorded. See Wiener (n 3) 1513; Julian Morris (n 20); Gardiner (n 24).

<sup>25</sup> Wiener (n 3) 1514.

<sup>26</sup> *Ibid.* 1515; Sunstein, “Beyond the Precautionary Principle” (n 5).

<sup>27</sup> Gardiner (n 24) 37.

<sup>28</sup> Julian Morris (n 20); Wiener and Rogers (n 5).

<sup>29</sup> Wiener refers to this version as “uncertain risk justifies action”. Wiener (n 3) 1515.

<sup>30</sup> On the difference between risk and uncertainty, see Knight (n 4); Kay and King (n 4). On the conditions of application of the precautionary principle, see Gardiner (n 24); Wiener (n 3).

<sup>31</sup> Some argue that all risks are uncertain. See Wiener: “All risks are probabilistic and uncertain because we can never know the future with complete certainty. Thus, all decisions about the future must be made in the face of uncertainty. We can never be completely certain that something will cause harm; we never have certainty about the risks we incur, or about the opportunities we seek.” Wiener (n 3) 1511–12.

<sup>32</sup> Note that Art 191 of the TFEU does not provide any definition of the precautionary principle.

<sup>33</sup> For a criticism of the use of the PP in the EU, see Majone (n 5).

<sup>34</sup> The language of the communication suggests that different versions of the precautionary principle may be used in the context of EU law. See, in particular, §6.4 which refers to “one way of applying the precautionary principle” by shifting the burden of proof for producing scientific evidence. Commission of the European Communities (n 20) 20.

<sup>35</sup> For instance, in Case C-180/96, *United Kingdom v Commission*, ECLI:EU:C:1998:192 (otherwise known as the BSE judgment), the European Court of Justice (now Court of Justice of the EU) held that “[w]here there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.” Para 99. This definition became the general definition of the precautionary principle and was reaffirmed on numerous occasions, including in Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, para 139. For an overview of how the EU Courts developed the principle, see Alemanno, “The Shaping of the Precautionary Principle by European Courts: From Scientific Uncertainty to Legal Certainty” (n 6).

referred to, for instance, when prior approval is required or when public authorities or users demonstrate the nature of a danger and the level of risk of a product or process, the effect of which is to shift the burden of proof upon “the producer, manufacturer or importer.”<sup>36</sup>

Note that regimes of risk regulation are notoriously varied; it is therefore to be expected that different versions of the principle apply within the same institutional framework depending on the regulated areas, risk tolerances, approaches to standard-setting, and institutional architecture.<sup>37</sup> In this sense, the different versions of the principle used by the EC do not represent an anomaly; context matters.

According to the Commission, the precautionary principle provides a structured framework for balancing the rights of individuals with the need to reduce the risk of adverse effects to the environment, human, animal or plant health.<sup>38</sup> To this end, the communication identifies two components of the principle: (1) whether to act; and (2) how to act. In order to answer the first component, two prerequisites must be satisfied: (a) the existence of potentially dangerous effects resulting from a product, phenomenon or procedure; and (b) scientific uncertainty as to the probability of the risk of them materialising.<sup>39</sup> Note that the decision to act is for the Commission an “eminently political decision,” which will vary depending on the “acceptable level of risk” that a society is willing to take.<sup>40</sup> Again, context matters.

If the principle provides some guidance as to whether regulatory or non-regulatory intervention is warranted, the principle does not, in and of itself, dictate the types of regulatory measures to be adopted: a ban, a mandate, a warning? Thus, when deciding how to act, the Commission does not prescribe any particular regulatory measures; instead, it lists six general principles upon which precautionary measures should be based.<sup>41</sup> First, measures should be proportional to the desired level of protection, noting that they “must not aim at zero risk, something which rarely exists.”<sup>42</sup> Second, they should be non-discriminatory in their application such as like cases should be treated alike and unlike cases unlike.<sup>43</sup> Third, they should be consistent with previous measures adopted in similar circumstances or using similar approaches. Fourth, and most importantly for the purpose of this article, precautionary measures should examine the benefits and costs of all forms of intervention available (ie action and inaction) both in the long term *and* in the short term.<sup>44</sup> In this sense, when comparing the likely positive and negative consequences of different courses of action, regard must be given to their long-term effects, which may affect the well-being of future generations.<sup>45</sup> Note that in the process of evaluating the pros and cons of a measure, a comprehensive assessment has to be carried out including

<sup>36</sup> Commission of the European Communities (n 20) 4. Note that the communication is quick to point out that this approach may not constitute a general rule.

<sup>37</sup> On regimes of risk regulation, see Hood, Rothstein and Baldwin (n 5) 6.

<sup>38</sup> Commission of the European Communities (n 20) para 1.

<sup>39</sup> In the words of the communication, “[t]he precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data”. *Ibid.* 13.

<sup>40</sup> *Ibid.* 15. This “acceptable level of risk” is also dependent upon the values and preferences of a given society. For further analysis, see Renn (n 5).

<sup>41</sup> Commission of the European Communities (n 20).

<sup>42</sup> *Ibid.* 6.3.1.

<sup>43</sup> *Ibid.* 6.3.2.

<sup>44</sup> *Ibid.* 6.3.4.

<sup>45</sup> *Ibid.* 7. The communication also specifies that the long-term effects of measures must be taken into account when assessing their proportionality (*ibid.* 6.3.1.)

economic and non-economic considerations. Fifth, measures should be constantly reviewed in light of scientific developments and, finally, they should be capable of assigning responsibility.<sup>46</sup>

Sometimes, precautionary measures may be understood as efforts to avoid the worst-case scenario; this is known as the maximin rule<sup>47</sup> or the Rawlsian Core Precautionary Principle.<sup>48</sup> Under the maximin rule, regulators identify all different courses of actions and their worst possible outcome before choosing the action that carries the least-worst outcome.<sup>49</sup> Put differently, regulators may decide to take aggressive regulatory measures in order to eliminate, or significantly decrease, the risk of worst-case scenarios. As noted by Rawls, the maximin rule may constitute an appealing strategy in three circumstances: (1) under conditions of genuine, epistemic, uncertainty;<sup>50</sup> (2) when the value of what is at stake is such that there is little additional gain above what is guaranteed by the maximin approach; and, (3) in situations of “grave risks.”<sup>51</sup> In the words of Gardiner,

“[i]f one really were faced with the genuine possibility of disaster, cared little for the potential gains to be made by avoiding disaster and had no reliable information about how likely the disaster was to occur, then, other things being equal, choosing to run the risk might well seem like a foolhardy and thereby extreme option.”<sup>52</sup>

Interestingly, the EC communication on the precautionary principle does refer to the maximin rule, even though it does not explicitly mention it. In Annex III, it notes that,

“[w]hen the available data are inadequate or non-conclusive, a prudent and cautious approach to environmental protection, health or safety could be to opt for the worst-case hypothesis. When such hypotheses are accumulated, this will lead to an exaggeration of the real risk but gives a certain assurance that it will not be underestimated.”<sup>53</sup>

While the purpose of this paper is not to assess whether this definition is appropriate, suffice it to say that the threshold for triggering its application may be too low. In any event, when the costs of eliminating the worst-case scenario are not too high, but the worst-case scenario is grave – for instance, measured in terms of millions of deaths during the onset of a pandemic – one may be excused for adopting the maximin rule as the rationale of otherwise extreme regulatory measures.<sup>54</sup>

With this background in mind, the next part identifies the regulatory measures adopted by the Irish government during the pandemic in relation to school closures and analyses the extent to which these measures may be said to rely upon one or several versions of the precautionary principle.

<sup>46</sup> Commission of the European Communities (n 20) para 6.4.

<sup>47</sup> As pointed out by Gardiner, “‘maximin’ means ‘maximize the minimum.’” Gardiner (n 24) 45.

<sup>48</sup> Sunstein, “Maximin” (n 24); Sunstein, *Averting Catastrophe* (n 4); Gardiner (n 24); J Rawls, *A Theory of Justice* (Rev ed, Belknap Press of Harvard University Press 1999).

<sup>49</sup> Gardiner (n 24) 45.

<sup>50</sup> For a summary of the difference between objective and subjective probabilities, see Kay and King (n 4).

<sup>51</sup> Rawls (n 49) 134.

<sup>52</sup> Gardiner (n 24) 49.

<sup>53</sup> Commission of the European Communities (n 20) 28.

<sup>54</sup> See Sunstein, *Averting Catastrophe* (n 4); Gardiner (n 24).

### III. Legal rationale of governmental decisions relating to school closure

The statutory regime for restrictions on school attendance in order to prevent the spread of an infectious disease is provided by section 31 of the Health Act 1947, which confers a regulatory power on the Minister for Health. Section 10 of the Health Act 2020 amends section 31 of the Health Act 1947 by inserting section 31(A), which delegates the power to the Minister for Health to make regulations and introduce measures to slow down the spread of Covid-19.<sup>55</sup> In particular, pursuant to paragraph h, regulations may provide for safeguards to be put in place by schools' managers, including the temporary closure of such facilities to prevent, minimise, limit, or slow the spread of Covid-19.<sup>56</sup>

On 12 March 2020, the Irish government announced a series of "social distancing" measures, including the temporarily closure of all educational institutions for an initial period of two weeks in order to "support efforts to contain the spread of Covid-19."<sup>57</sup> These regulatory measures were renewed on several occasions throughout the pandemic.

For the purpose of analysing the legal rationale of these measures, the paper has identified three phases. The first phase covers the initial period of the pandemic from March 2020 until the end of the school year 2019/20 in June 2020.<sup>58</sup> During this phase, all school premises were directed to close. The second phase covers the period from end of August/early September 2020, which corresponds to the commencement of the school year 2020/21, until December 2020. This period was marked by a re-opening of schools, albeit with a caveat. The third phase extends from January to June 2021, which marks the end of the 2020/21 school year. At the end of December 2020, stronger restrictions were reimposed, thereby closing school premises until March 2021.

#### I. Phase I: March–June 2020

The closure of all school premises was announced by the Taoiseach on 12 March 2020 following the recommendation of the National Public Health Emergency Team (NPHE).<sup>59</sup> This measure took effect from 6pm on the 12 March for a period of two weeks.<sup>60</sup> It was extended on 24 March until 19 April 2020<sup>61</sup> and ultimately until the end of the school year 2019/2020. Interestingly, this measure did not rely on the statutory framework relating to restrictions on school attendance mentioned above. Similarly, no statutory instrument can be located ordering school closure. Instead, this measure was communicated by way of

<sup>55</sup> Section 31 A (1) of the Health Act 2020. Note that the application of Section 10 was extended until February 2022.

<sup>56</sup> Section 31A(1)(h) of the Health Act 2020 provides "without prejudice to the generality of the foregoing paragraphs, the safeguards required to be put in place by managers (however described) of schools, including language schools, creches or other childcare facilities, universities or other educational facilities (including the temporary closure of such facilities) to prevent, minimise, limit, or slow the risk of infection of persons attending such premises of being infected with Covid-19."

<sup>57</sup> Department of Education and Skills, Press Release, 12 March 2020 <<https://www.education.ie/en/Press-Events/Press-Releases/2020-press-releases/12-march-2020-statement-from-the-department-of-education-and-skills.html>> (last accessed 12 March 2024).

<sup>58</sup> There was some summer provision for students with special needs.

<sup>59</sup> Letter from the Office of the Chief Medical Officer to the Minister for Health, 12 March 2020, <<https://www.gov.ie/pdf/?file=https://assets.gov.ie/73596/367ce30c2df64207b665b78d63d07a9c.pdf#page=null>> (last accessed 12 March 2024).

<sup>60</sup> Statement from the Department of Education and Skills, 12 March 2020, <<https://www.gov.ie/en/press-release/92724a-covid-19-statement-from-the-department-of-education-and-skills/>> (last accessed 12 March 2024).

<sup>61</sup> Statement from the Department of Education and Skills, 24 March, 2020, <<https://www.gov.ie/en/press-release/4366e7-statement-from-the-department-of-education-and-skills-on-covid-19/>> (last accessed 12 March 2024).

announcement by the Taoiseach and the Department of Education.<sup>62</sup> Thus, what was its legal rationale?<sup>63</sup>

At the onset of the pandemic, it was generally accepted that the situation was one of epistemic uncertainty. As early as January 2020, the European Centre for Disease Prevention and Control (ECDC) pointed out a “substantial level of uncertainty regarding the epidemiological characteristics” of this novel coronavirus.<sup>64</sup> This substantial degree of uncertainty was maintained in the ECDC six update of its rapid risk assessment published on 12 March 2020,<sup>65</sup> a day after the World Health Organisation declared Covid 19 a global pandemic. Of interest to this paper, the update noted considerable uncertainty in the evidence of children in transmitting the disease<sup>66</sup> and in the impact of generalised school closure in limiting the progression of the Covid-19 pandemic.<sup>67</sup> Yet, when the NPHE recommended school closures on 12 March, the situation was one of “grave risks” in terms of potential number of deaths and incapacity of the healthcare system to cope with the rapid spread of the virus. The predictions made by the ECDC on 12 March suggested that if the pandemic progressed on its current course and if governments did not adopt strong countermeasures to slow down the spread of the virus, the ICU capacity of most EU/EEA countries would be exceeded by the end of March 2020.<sup>68</sup>

In this context, the total closure of school during the first few months of the pandemic was part of an emergency response<sup>69</sup> that led to the adoption of aggressive regulatory measures to suppress the virus by “breaking chains of transmission.”<sup>70</sup> Due to the uncertainty surrounding the state of knowledge relating to Covid-19, the decision to close schools was based on what was known of the impact of pre-emptive early school closures on transmission of pandemic influenza.<sup>71</sup>

This aggressive response was justified by the maximin rule, identified above, which provides a strategy for eliminating the risk of the worst-case scenario. As noted by the Government Task Force on Emergency Planning in its 2020 national risk assessment, the early months of the pandemic “presented the reasonable worst-case scenario.”<sup>72</sup> Thus, as the economic and non-economic costs of social distancing were not too high, it was

<sup>62</sup> On the legal basis of the Government’s decision to close schools, see C Casey, “Executive Power and the Right to Primary Education: The Case of School Closures” (*Covid-19 Law and Human Rights Observatory*, 2021 March) <<https://tcldlaw.blogspot.com/2021/03/executive-power-and-right-to-primary.html>>.

<sup>63</sup> On the legal basis of the decision to close schools, see *ibid*.

<sup>64</sup> European Centre for Disease Prevention and Control (ECDC), Rapid Risk Assessment: Cluster of pneumonia cases caused by a novel coronavirus, Wuhan, China, 17 January 2020 (ECDC: Stockholm).

<sup>65</sup> European Centre for Disease Prevention and Control (ECDC), Rapid Risk Assessment: Novel coronavirus disease 2019 (COVID-19) pandemic: increased transmission in the EU/EEA and the UK – sixth update, 12 March 2020 (ECDC: Stockholm).

<sup>66</sup> ECDC, “Novel Coronavirus Disease 2019 (COVID-19) Pandemic: Increased Transmission in the EU/EEA and the UK” (ECDC 2020) Six update 7.

<sup>67</sup> *Ibid*, 2.

<sup>68</sup> *Ibid*, 13.

<sup>69</sup> Although Ireland did not declare a constitutional state of emergency, its approach was similar to one with a delegation of broad regulatory powers to the Minister for Health. See further C Casey, O Doyle and D Kenny, “The Irish State’s COVID-19 Response and the Rule of Law: Causes for Concern” (2021) 110 *Studies: An Irish Quarterly Review* 446.

<sup>70</sup> Government of Ireland, “A National Risk Assessment for Ireland 2020” (Government of Ireland 2020) 30 <<https://www.gov.ie/ga/preasraitis/5e685-national-risk-assessment-for-ireland-2020/>>. Note that this strategy was adopted by most EU governments, save for Sweden and the UK, at the early stage of the pandemic. For further analysis, see Alemanno, who argues that during Phase 1 of the pandemic, the most “responsible course of action was to take the most risk-averse position”. A Alemanno, “The European Response to COVID-19: From Regulatory Emulation to Regulatory Coordination?” (2020) 11 *European Journal of Risk Regulation* 307.

<sup>71</sup> European Centre for Disease Prevention and Control (ECDC), COVID-19 in Children and the Role of School Settings in COVID-19 Transmission, 6 August 2020 (ECDC: Stockholm) 2.

<sup>72</sup> Government of Ireland (n 71) 30.



legitimate to close schools during phase 1 so as to “flatten the curb” and eliminate the risk of a saturated healthcare system. In addition, as per a conventional cost-benefit analysis, the benefits that accrued from this measure in terms of saved lives significantly outweighed the costs.<sup>73</sup>

If, however, phase 1 of the pandemic was characterised by epistemic uncertainty and grave risks, thereby justifying the application of the maximin rule, the same may not be said about phase 2.

## 2. Phase 2: September–December 2020

In July 2020, the government published a roadmap for the reopening of schools at the end August/early September 2020.<sup>74</sup> Making the reopening of schools a top priority, the report highlighted the importance of education for the health and well-being of children, recalled the constitutional status of the right to free primary education, and reviewed the impacts that school closures had on students during phase 1.<sup>75</sup> Accordingly, schools reopened in September 2020 with a number of protective measures in place, such as the promotion of good hand hygiene, enhanced cleaning regimes in schools, physical distancing in the classroom, the use of face masks, and the restriction of attendance of pupils/students and staff who were unwell.<sup>76</sup> Schools remained open until December 2020, even though the whole country was placed into lockdown on 21 October 2020 until 1 December.<sup>77</sup> During this period, a number of schools experienced temporarily closure either at an individual level or more localised.<sup>78</sup> Recall that under Section 31A(1)(h) of the Health Act 2020, school managers may put safeguards in place, including the temporary closure of school facilities to prevent, minimise, limit, or slow the spread of Covid-19.

While the epidemiology of the virus was still uncertain, the situation was not one of epistemic uncertainty. As noted by the Government Task Force on Emergency Planning in its 2020 national risk assessment, the emergency response seen in the early months of the pandemic was replaced by a “medium-term approach to manage risks” in September 2020.<sup>79</sup>

In addition, phase 2 was characterised by an increased awareness of the negative impacts that school closures had on children.<sup>80</sup> For instance, during the Summer 2020, the

<sup>73</sup> See in particular Alemanno, “The European Response to COVID-19” (n 71); Sunstein, *Averting Catastrophe* (n 4).

<sup>74</sup> Department of Education and Skills, “Reopening Our Schools: The Roadmap for the Full Return to School” (Government of Ireland 2020).

<sup>75</sup> *Ibid.*, 7.

<sup>76</sup> Department of Education and Skills (n 75).

<sup>77</sup> The Government announced level 5 lockdown restrictions on 19 October 2020, which included, amongst other things, a stay at home order, a 5 km travel restriction for exercise, the closure of non-essential businesses and services, a limited capacity of public transport, restrictions on pubs, cafes and restaurants to provide take-away and delivery services only and a ban on organised indoor or outdoor events. See Department of the Taoiseach press release, “Ireland placed on Level 5 of the Plan for Living with Covid-19”, 19 October 2020, <<https://www.gov.ie/en/press-release/66269-ireland-placed-on-level-5-of-the-plan-for-living-with-covid/>> (last accessed 12 March 2024).

<sup>78</sup> For instance, in September 2020, a class in a Dublin school was sent home after a positive case was detected (<<https://www.rte.ie/news/education/2020/0901/1162526-coronavirus-school/>>); schools in Kerry and Clare also closed for one week (<<https://www.irishexaminer.com/news/munster/arid-40042496.html>> (last accessed 12 March 2024)).

<sup>79</sup> Government of Ireland (n 71) 10.

<sup>80</sup> ESRI and others, “Learning for All? Second-Level Education in Ireland during COVID-19” (ESRI 2020); ESRI and others, “The Implications of the COVID-19 Pandemic for Policy in Relation to Children and Young People: A Research Review” (ESRI 2020); W Van Lancker and Z Parolin, “COVID-19, School Closures, and Child Poverty: A Social Crisis in the Making” (2020) 5 *The Lancet Public Health* e243; European Centre for Disease Prevention and Control (ECDC) (n 72); UNICEF and others, “Framework for Reopening Schools” (2020); World Bank, “The Covid-19 Pandemic: Shocks to Education and Policy Responses” (World Bank 2020).

ECDC noted that while the effect of school closures on the transmission of Covid-19 in the EU/EEA/UK and globally was largely unknown, “the effect of school closures on children’s health and well-being [was] well-documented and researched over the years, following influenza pandemics and school closures during the summer months.”<sup>81</sup> In particular, it was noted that schools’ closure widened inequalities,<sup>82</sup> increased dropouts, increased domestic violence, and had long-term consequences for the economy and society more generally.<sup>83</sup> Finally, the ECDC noted that the reopening of schools in some EU countries had not led to an increase in child-to-child transmission of the virus. Available evidence suggested at the time that transmission among children in schools [was] less efficient for COVID-19 than for other respiratory viruses such as influenza.<sup>84</sup> Thus, the report concluded that child-to-child transmission in schools was uncommon and not the primary cause of infection of children; children were not the primary cause of transmission to adults in schools; to the extent that children may be infected by an adult, there was little evidence suggesting that this was occurring within schools; and, finally, the available evidence suggested that closures of childcare and educational institutions were unlikely to be an effective single control measure for community transmission of COVID-19 and such closures would be unlikely to provide significant additional protection of children’s healthy.<sup>85</sup>

These negative impacts of school closures were, to some extent, considered by the Government in its roadmap for the full return to schools. Of interest to this paper, the report called for the adoption of a “balanced approach” whereby the need for “a practical and sensible level of caution” should be balanced against the need to provide a supportive environment for pupils/students [. . .] where teachers felt able to engage with pupils in a way that supported their learning.<sup>86</sup> Thus, what this balanced approach suggests is that a version of the precautionary principle<sup>87</sup> was influential in the decision-making process and, more importantly, that a form of impacts assessment was carried out even though no written trace can be identified. While correlation is not causation, it is no coincidence that in light of the numerous reports documenting the negative impacts that school closures had on children during phase 1 and the absence of evidence suggesting that keeping schools open would increase the rate of transmission in the community, the government decided to keep schools open while placing the entire country back into lockdown in October 2020.

Yet, this application of the precautionary principle in conjunction with a form of impacts assessment was short-lived. Following a series of announcements by the government, Ireland was placed under lockdown restrictions from the end of December 2020 and schools were ordered to close again, some of them until March 2021.<sup>88</sup>

<sup>81</sup> European Centre for Disease Prevention and Control (ECDC) (n 72) 3.

<sup>82</sup> The pandemic led to an unequal distribution of its impacts, with children from disadvantaged backgrounds and with special educational needs suffering the bulk of its negative effects.

<sup>83</sup> European Centre for Disease Prevention and Control (ECDC) (n 72) 4.

<sup>84</sup> *Ibid*, 11.

<sup>85</sup> European Centre for Disease Prevention and Control (ECDC) (n 72).

<sup>86</sup> Department of Education and Skills (n 75) 7.

<sup>87</sup> Probably version 2 of the Wiener framework, although the identification of which version was applicable is to some extent less important.

<sup>88</sup> Department of the Taoiseach, “Ireland placed on full Level 5 Restrictions of the Plan for Living with COVID-19,” Press release, 30 December 2020, <<https://www.gov.ie/en/press-release/066ce-ireland-placed-on-full-level-5-restrictions-of-the-plan-for-living-with-covid-19/>> (last accessed 12 March 2024).

### 3. Phase 3: January–June 2021

On 6 January 2021, the government announced that schools would remain closed until 31 January.<sup>89</sup> This decision was subsequently extended until March 2021. Exceptions were made for special schools, which began reopening on 11 February 2021 at 50% capacity and special classes in mainstream schools on 22 February 2021.<sup>90</sup> From 1 March 2021, a gradual reopening of schools was announced with primary school pupils returning to school on 15 March<sup>91</sup> and the full reopening of all schools on 12 April 2021.<sup>92</sup>

The decision to keep schools closed on 6 January 2021 was based on the advice of the NPHE published a day in advance. In his letter to the Minister for Health, the Chief Medical Officer noted that at its meeting of the 30 December 2020, the NPHE advised the government to reopen schools on 11 January 2021. The rationale for this advice was based on a standard cost-benefit analysis:

“the known negative impacts of school closures on children (including student mental health, wellbeing, development, educational attainment and overall health outcomes) outweighed the risks of reopening in terms of potential direct health risks to children and staff from COVID-19 (with evidence to date confirming that schools are a safe and protected environment) and the wider impact of school opening on community transmission levels.”<sup>93</sup>

The letter further noted that there was “very little evidence of transmission in schools” and that the reopening of schools in August 2020 “was not associated with any increase in the growth rate of the infection across the population as a whole”<sup>94</sup> – a finding similar to the conclusion of the ECDC in its Summer 2020 report and subsequently reiterated by the Department of Education in a 2021 report.<sup>95</sup> Yet, the letter concluded:

“while the experience from September to December 2020 has clearly demonstrated that schools are in themselves a safe environment, the current epidemiological situation has deteriorated to a point where the significant levels of mobility and linked activity that the full reopening of schools would generate constitutes a very significant additional risk in the context of what are already unprecedented levels of disease transmission in the community. It is important to note that this advice is not based on a changed assessment of the risks in relation to transmission levels in schools. Rather, it is a reflection of the overall epidemiological situation and the absolute need now to reduce all opportunities for transmission.”<sup>96</sup>

<sup>89</sup> Department of Education, “Minister Foley confirms that schools will remain closed to students” Press release, 7 January 2021, <<https://www.gov.ie/en/press-release/11176-minister-foley-confirms-that-schools-will-remain-closed-to-students/>> (last accessed 12 March 2024).

<sup>90</sup> Department of Education, Press release, 1 February 2021, <<https://www.gov.ie/en/press-release/6f91d-ministers-foley-and-madigan-welcome-agreed-plan-for-return-to-in-school-learning-for-children-with-special-educational-needs-at-primary-level/>> (last accessed 12 March 2024).

<sup>91</sup> Department of Education, “Letter to Primary Principals,” 8 March 2021, <<https://www.into.ie/app/uploads/2019/07/Letter-to-Primary-Principals-8Mar21.pdf>> (last accessed 12 March 2024).

<sup>92</sup> Department of the Taoiseach, “Briefing on the government’s response to COVID-19,” 3 March 2021, <<https://www.gov.ie/en/publication/0843e-briefing-on-government-measures-in-response-to-covid-19-wednesday-3-march-2021/#>> (last accessed 12 March 2024).

<sup>93</sup> Letter from CMO to Minister for Health re COVID-19 (Coronavirus), 5 January 2021, <<https://www.gov.ie/pdf/?file=https://assets.gov.ie/118212/b00522b8-7deb-4f61-9c1c-9c8df6185a00.pdf#page=null>> (last accessed 12 March 2024).

<sup>94</sup> *Ibid.*, 3.

<sup>95</sup> Department of Education, “Return to school: Summary of research – September–December 2020” (February 2021, Dublin).

<sup>96</sup> Letter from CMO to Minister for Health re COVID-19 (Coronavirus), 5 January 2021, p.7.

This letter from the CMO needs to be read in conjunction with two additional letters from 30 December 2020 and 7 January 2021 in order to understand the rationale underneath this advice. In his letter dated 30 December 2020, the CMO reported that the epidemiological situation of Covid-19 in Ireland was of “immense concern” and represented “an immediate and grave threat to all key public health priorities [...] and the continued delivery of education and childcare services.”<sup>97</sup> The approach adopted in this letter was that of suppression of viral transmission, as opposed to mitigation, with a view to reducing the reproduction number (R) below 1. This approach was reiterated on several occasions in the letters dated 7 January 2021, 14 January 2021, and 21 January 2021. In effect, what the wording of these letters suggests is that the advice of the NPHE was based again on the worst-case scenario, using the maximin rule as a regulatory strategy to eliminate or reduce the risk of the worst-case scenario.

As seen above, this strategy was used during the onset of the pandemic. There is, however, a major difference between the two phases: while phase 1 was characterised by a situation of epistemic uncertainty and the application of the maximin rule was justified by a conventional cost-benefit analysis, phase 3 was not. While there was uncertainty as to the epidemiology of the virus in light of its constant mutations and a proportion of the population identified as highly vulnerable, the application of the maximin rule in phase 3 was in open contradiction with a conventional cost-benefit analysis as acknowledged by the CMO in his letter of 5 January 2021.

Thus, it results from the above analysis that two very different applications of the maximin rule, which is, to recall, a version of the precautionary principle, constituted the rationale for school closures. One application was supported by a conventional cost-benefit analysis (phase 1), the other was not (phase 3). To the extent that these findings rerun the debate between precaution and impact assessment, the next part analyses the (relatively) recent decisions of the General Court in *BASF* and *Bayer CropScience*.

#### IV. Precautionary principle and impact assessment in the caselaw of the General Court

Since the 2000 EC communication, the precautionary principle has been referred to in decisions of the EU courts on numerous occasions.<sup>98</sup> While a detailed review of the case law is beyond the scope of this article, suffice it to say that recent development shows greater symmetry between the position of the Courts and the EC communication.<sup>99</sup>

Up until 2018, many decisions based on the precautionary principle were made absent of a risk assessment.<sup>100</sup> In *Pfizer and Alpharma*, no risk assessment was performed, and the Court of First Instance (now General Court of the EU) did not sanction the risk manager for

<sup>97</sup> Letter from CMO to Minister for Health re COVID-19 (Coronavirus), 30 December 2020, <<https://www.gov.ie/pdf/?file=https://assets.gov.ie/117748/e3b13a2c-0668-40a9-94bf-8bc774395b63.pdf#page=null>> (last accessed 12 March 2024).

<sup>98</sup> One source counts 147 references to the principle in the CJEU and GC case law between 2000 and 2019. For further analysis, see De Smedt and Vos (n 6) 176.

<sup>99</sup> For an overview of EU cases referring to the EC communication prior to 2014, see R Lofstedt, “The Precautionary Principle in the EU: Why a Formal Review Is Long Overdue” (2014) 16 Risk Management 137.

<sup>100</sup> This was the case in Case T-70/99, *Alpharma v Council*, ECLI:EU:T:2002:210, Case T-392/02 R, *Solvay Pharmaceuticals v Council*, ECLI:EU:T:2003:277, and Case C-343/09, *Afton Chemical*, ECLI:EU:C:2010:419, in which the Commission or Council did not conduct a risk assessment before invoking the precautionary principle. De Smedt and Vos (n 6) 179. In case T-229/04, *Sweden v. Commission* (otherwise known as *Paraquat*), ECLI:EU:T:2007:217, and case C-77/09, *Gowan Comércio*, ECLI:EU:C:2010:803, the CJEU accepted the correct invocation of the precautionary principle without scrutinising whether the risk assessment was carried out by a risk assessor. For further analysis, see A Alemanno, “Case C-79/09, *Gowan Comércio Internacional e Serviços Lda v. Ministero Della Salute*, Judgment of the Court of Justice (Second Chamber) of 22 December 2010” (2011) 48 Common Market Law Review 1329.

not undertaking such an assessment prior to invoking the precautionary principle. In fact, the Court held that a ban could be adopted without a risk assessment and against the advice of the scientific committee (when consulted).<sup>101</sup> In *Gowan*, the existence of scientific uncertainty for triggering the application of the principle was identified by the risk manager, as opposed to the risk assessor, thereby giving support to considerations other than science.<sup>102</sup>

The twin cases of *BASF v Commission* and *Bayer CropScience v Commission* depart from previous decisions and may augur a new trend towards a risk-based approach to the precautionary principle.<sup>103</sup> In both cases, the General Court based its analysis on the framework of the EC communication and signalled a willingness to exercise greater scrutiny on the procedural steps associated with the principle. In particular, the General Court clarified two procedural requirements. First, it reaffirmed the obligation to carry out a scientific risk assessment before invoking the principle,<sup>104</sup> making it clear that the purpose of a risk assessment is not to provide conclusive scientific evidence of a phenomenon and its risks as it cannot under conditions of uncertainty; rather, its purpose is to provide an “estimation [...] of the probability, of the frequency and severity of known or potential adverse [...] effects.”<sup>105</sup> Put differently, it is a tool for forecasting future scenarios under conditions of uncertainty.<sup>106</sup>

Second, and in line with the EC communication, the General Court imposed an obligation on the risk manager (in both cases, the Commission) to carry out an impact assessment pursuant to the precautionary principle. While the General Court noted that there is no obligation to “initiate a specific assessment procedure culminating [...] in a formal, written assessment report,”<sup>107</sup> the Commission “was obliged, pursuant to the precautionary principle, to carry out an impact assessment of the measures proposed.”<sup>108</sup>

To be clear, the requirement to carry out an impact assessment of some form (such as a cost/benefit analysis) when adopting precautionary measures, while surprising to some, does not constitute a new obligation.<sup>109</sup> In *Pfizer*, the Court of First Instance considered that a “cost/benefit analysis is a particular expression of the principle of proportionality in cases involving risk management.”<sup>110</sup> Thus, when reviewing whether a measure breaches the principle of proportionality, the court will consider “whether, in the framework of a cost/benefit analysis, those disadvantages [of the measure] are disproportionate by comparison with the advantages which would ensure if no action were taken.”<sup>111</sup> Similarly,

<sup>101</sup> For further analysis, see De Smedt and Vos (n 6); Wiener (n 12).

<sup>102</sup> Case C-77/09, *Gowan Comércio*, ECLI:EU:C:2010:803, in which public concern seems to have play a key role. For further analysis, see Alemanno, “Case C-79/09, *Gowan Comércio Internacional e Serviços Lda v. Ministero Della Salute*, Judgment of the Court of Justice (Second Chamber) of 22 December 2010” (n 101).

<sup>103</sup> Case T-584/13 *BASF Agro and Others v Commission*, EUCLI:EU:T:2018:279, para 58 onwards; Case T-429/13 *Bayer CropScience v Commission*, ECLI:EU:T:2018:280, para 111 onwards.

<sup>104</sup> Interestingly, this obligation was affirmed in Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, para 155.

<sup>105</sup> Annex III of the communication, cited in Case T-584/13 *BASF Agro and Others v Commission*, EUCLI:EU:T:2018:279, para 63. Interestingly, the purpose of a risk assessment was also mentioned in Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, para 148.

<sup>106</sup> As noted by Wiener, the Court of First instance in *Pfizer* may have misunderstood the purpose of risk assessment Wiener (n 12) 481.

<sup>107</sup> Case T-584/13 *BASF Agro and Others v Commission*, EUCLI:EU:T:2018:279, para 162.

<sup>108</sup> Case T-584/13 *BASF Agro and Others v Commission*, EUCLI:EU:T:2018:279, para 171.

<sup>109</sup> Note that a cost/benefit analysis is a form of an impact assessment. For a different interpretation, see L Krämer, “Precautionary Principle, Cost-Benefit Analysis and Impact Assessment – Comment on General Court of 17-5-2018, Case T-584/13, *Basf Agro a.o. v. Commission*” (2018) 15 *Journal for European Environmental & Planning Law* 376.

<sup>110</sup> Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, para 410.

<sup>111</sup> Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, para 413.

in *BASF* the General Court reaffirms this link between impact assessment and the principle of proportionality.<sup>112</sup>

What is perhaps surprising is that, instead of relying on *Pfizer*, the General Court relied on the EC communication, in particular point 6.3.4, which requires an examination of the benefits and costs of action and lack of action.<sup>113</sup> The EC communication is a non-binding document.<sup>114</sup> While a degree of discretion regarding the methods of analysis was reaffirmed, the General Court noted that the Commission was under an obligation to compare the “effects, positive and negative, economic and otherwise” of the intended measure with those of inaction.<sup>115</sup> If the General Court was satisfied in *Bayer CropScience* that the Commission had acquainted itself with such an obligation, in *BASF* the Commission failed to provide evidence demonstrating that such an impact assessment had been carried out.<sup>116</sup> Interestingly, on appeal from *Bayer CropScience*, the CJEU did not object to the existence of such an obligation, which it qualified as “independent” from the regulatory framework under review.<sup>117</sup> In fact, it viewed the discretion that risk managers have with respect to the scope and form of the impact assessment as falling within the application of the principle of proportionality, which is implicitly incorporated in the regulatory framework under review.<sup>118</sup>

Thus, three points emerge from the above development: first, when adopting measures based on the precautionary principle, the risk manager is under an obligation to carry out an impact assessment, which analyses the effects of the intended measures and compares them with the alternative(s). Second, this requirement to carry out an impact assessment is no more than an “expression” of the principle of proportionality, which is a long-standing EU law principle.<sup>119</sup> Third, this trend developed by the EU Courts is in harmony with the Commission’s Better Regulation agenda, which requires an impact assessment for any legislative “initiatives that are likely to have significant economic, environmental or social impacts or which entail significant spending and where the Commission has a choice of policy option.”<sup>120</sup> As *per* the Commission, impact assessments should be, *inter alia*, comprehensive in the sense that they consider all impacts (economic and non-economic, short and long-term) and proportionate by comparison to other options – a definition that is reminiscent of the caselaw above.<sup>121</sup>

<sup>112</sup> Case T-584/13 *BASF Agro and Others v Commission*, EUCLI:EU:T:2018:279, para 170: “the obligation [...] to carry out an impact assessment is ultimately no more than a specific expression of the principle of proportionality.”

<sup>113</sup> Case T-584/13 *BASF Agro and Others v Commission*, EUCLI:EU:T:2018:279, para 161; Case T-429/13 *Bayer CropScience v Commission*, ECLI:EU:T:2018:280, para 458.

<sup>114</sup> On the legal effects of EU soft law, see G Gentile, “Ensuring Effective Judicial Review of EU Soft Law via the Action for Annulment before the EU Courts: A Plea for a Liberal-Constitutional Approach” (2020) 16 *European Constitutional Law Review* 466.

<sup>115</sup> Case T-429/13 *Bayer CropScience v Commission*, ECLI:EU:T:2018:280, para 460.

<sup>116</sup> Case T-584/13 *BASF Agro and Others v Commission*, EUCLI:EU:T:2018:279, para 164.

<sup>117</sup> Case C-499/18 P, *Bayer CropScience v Commission*, ECLI:EU:C:2021:367, para 176. For a different interpretation, see GC Leonelli, “Balancing Public Health and Environmental Protection and Economic Stakes? *Bayer CropScience* and the Court’s Defence of the EU Socially Acceptable Risk Approach” (2021) 58 *Common Market Law Review* 1845.

<sup>118</sup> Case C-499/18 P, *Bayer CropScience v Commission*, ECLI:EU:C:2021:367, para 169-170.

<sup>119</sup> See section IV below.

<sup>120</sup> European Commission (n 7) 30.

<sup>121</sup> *Ibid.*, 32.

## V. Conclusion: prospects for an evidence-based approach to precaution in EU risk regulation

The problems associated with the precautionary principle have long been documented in risk regulation scholarship.<sup>122</sup> For instance, its narrow focus on a single approach to risk and absence of distributional considerations do not reflect the fact that risk–risk trade-offs are inevitable and byproduct of any regulatory intervention, including precaution. The Irish experience of school closures during phase 3 of the pandemic reminds us of this reality: countervailing risks measured in terms of educational costs induced by school closures in an effort to eliminate one target risk (the spread of the virus).

But it does need to be this way. As illustrated by the decisions taken during phases 1 and 2, it is possible to marry a precautionary intervention with an impact assessment. In fact, their union may provide a procedural safeguard against discretionary decisions that have an impact on fundamental rights, especially under conditions of epistemic uncertainty. This, in turn, may provide the Courts with the necessary impetus for carrying greater scrutiny on precautionary measures.

The question of whether decisions based on the precautionary principle or based on impact assessment should be reviewed by the Courts is a long-standing debate that has generated much ink on both sides of the Atlantic.<sup>123</sup> There is not the space here to discuss and sort out the entire debate. Instead, what follows are three brief concluding observations emphasising the advantages of marrying these two regulatory frameworks.

First, if the decision to invoke the precautionary principle is mainly political,<sup>124</sup> the principle provides an administrative framework for structured-reasoning, which can be subject to judicial review.<sup>125</sup> As stated in the 2000 communication, the principle may not be invoked in order to justify arbitrary decisions.<sup>126</sup> Thus, commensurate with administrative law principles, decision-makers adopting precautionary measures are required to provide reasons for justifying their decisions and clarify how these decisions are made.<sup>127</sup> One medium for achieving this is through impact assessment. Recall that the precautionary principle supposes the existence of epistemic uncertainty. Under this condition, decision-makers may face political pressures to do something hastily without a “sound” assessment – an approach sometimes referred to as a “knee-jerk reaction”<sup>128</sup> – with a view to avoiding “*ex post* blame.”<sup>129</sup> In the context of the pandemic, it is legitimate to wonder whether political pressures may have influenced the decision to close Irish schools during phase 3. The requirement to conduct an impact assessment of some forms, such as a cost-benefit analysis, diminishes the likelihood of succumbing to these pressures. By comparing the pros and cons of different options and considering their overall impacts (both intended and unintended) on society, impact assessment provides a platform for debating the reasons upon which the

<sup>122</sup> Wiener (n 3); Majone (n 5); Sunstein, “Beyond the Precautionary Principle” (n 5).

<sup>123</sup> E Fisher, “Is the Precautionary Principle Justiciable?” (2001) 13 *Journal of Environmental Law* 315; E Fisher, JS Jones and R von Schomberg (eds), *Implementing the Precautionary Principle: Perspectives and Prospects* (Edward Elgar Publishing 2006); J Masur and EA Posner, “Cost-Benefit Analysis and the Judicial Role” (2018) 85 *The University of Chicago Law Review* 935; CR Sunstein, “Cost-Benefit Analysis and Arbitrariness Review” (2017) 41 *Harvard Environmental Law Review* 1; R Bull and J Ellig, “Judicial Review of Regulatory Impact Analysis: Why Not the Best?” (2017) 69 *Administrative Law Review* 725.

<sup>124</sup> Commission of the European Communities (n 20) para 5.2.1.

<sup>125</sup> E Fisher and R Harding, “The Precautionary Principle and Administrative Constitutionalism: The Development of Frameworks for Applying the Precautionary Principle” in E Fisher, JS Jones and R von Schomberg (eds), *Implementing the Precautionary Principle* (Edward Elgar Publishing 2006); E Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart 2010).

<sup>126</sup> Commission of the European Communities (n 20) para 5.1.

<sup>127</sup> Fisher and Harding (n 126).

<sup>128</sup> “Mandelkern Group on Better Regulation – Final Report” (2001) para 3.6.3.

<sup>129</sup> Barbara H Fried, “Facing Up To Risk” (2018) 10 *Journal of Legal Analysis* 175, 195.

decision is made and, in that sense, satisfies the transparency requirement of “good administration.”<sup>130</sup> Currently, the trend tilts in favour of reviewing impact assessments of regulators both in the US<sup>131</sup> and in the EU.<sup>132</sup>

Second, impact assessment is based on the principle of proportionality, which is not only a core general principle of EU law,<sup>133</sup> but also a principle of administrative law within many jurisdictions and therefore a ground for review. At the EU level, this link was referred to in two lines of cases: 1) review of EU legislations based on an alleged breach of the principle of proportionality,<sup>134</sup> and; 2) review of EU measures based on an alleged breach of the precautionary principle.<sup>135</sup> According to the principle of proportionality, EU law measures should not exceed what is “appropriate and necessary in order to achieve” their desired end and where there is a choice between several options, the least onerous options must be considered bearing in mind that the “disadvantages caused must not be disproportionate to the aims pursued.”<sup>136</sup> This latter limb of the principle is often referred to as proportionality *stricto sensu*; it requires a balancing exercise between fundamental rights. When linked with the precautionary principle, this balancing exercise is between the impacts associated with the restrictions and the environment or public health.<sup>137</sup> Within the Irish framework, suffice it to say that the principle of proportionality is also referred to in administrative law cases that involve fundamental rights.<sup>138</sup> Thus, when an administrative decision infringes upon a fundamental right, the Irish courts have incorporated a proportionality review within the reasonableness test.<sup>139</sup> It is questionable whether the decision to close Irish schools in January 2021 would satisfy proportionality *stricto sensu*.

Third, when exercising a discretionary power, decision-makers may give due regard to a range of considerations. While some considerations may be stated in a statute, others may not. This raises the question of what is relevant. To be clear, when managing risks and under conditions of uncertainty, this question of relevance is inextricably intertwined with evidence and normative claims.<sup>140</sup> Nonetheless, it is possible to hypothesise some considerations that would be relevant when adopting precautionary measures. For

<sup>130</sup> Wiener calls this “Warm Analysis”, Wiener (n 12) 483. On transparency of IA, see also A Alemanno, “Courts and Regulatory Impact Assessment” in CA Dunlop and CM Radaelli (eds), *Handbook on Regulatory Impact Assessment* (Edward Elgar Publishing 2016). On impact assessment as a “justification tool in court proceedings”, see D Keyaerts, “The Impact of Better Regulation in the Case Law of the European Court of Justice” (2012) 3 *European Journal of Risk Regulation* 241.

<sup>131</sup> For a review of the position in the US, see Masur and Posner (n 124); Sunstein, “Cost-Benefit Analysis and Arbitrariness Review” (n 124); Bull and Ellig (n 124).

<sup>132</sup> Alemanno, “Courts and Regulatory Impact Assessment” (n 131); Keyaerts (n 131); A Alemanno, “The Better Regulation Initiative at the Judicial Gate: A Trojan Horse within the Commission’s Walls or the Way Forward?” (2009) 15 *European Law Journal* 382.

<sup>133</sup> This principle is enshrined in Art 5.3 of the TEU. See also European Commission (n 7) 30.

<sup>134</sup> See Case C-58/08, *Vodafone and others*, ECLI:EU:C:2010:321 and Case C-310/04, *Spain v Council*, ECLI:EU:C:2006:521. See further Alemanno, “Courts and Regulatory Impact Assessment” (n 131).

<sup>135</sup> Case T-13/99, *Pfizer Animal Health SA v Council of the European Union*, ECLI:EU:T:2002:209, para 410; Case T-584/13 *BASF Agro and Others v Commission*, EUCLI:EU:T:2018:279, para 170.

<sup>136</sup> Case C-331/88 *The Queen v Minister of Agriculture, Fisheries and Food and Secretary of State for Health ex parte Fedesa and others* (1990) ECR I-4023, para 13; see also Pfizer, para 411.

<sup>137</sup> IG Lang, “‘Laws of Fear’ in the EU: The Precautionary Principle and Public Health Restrictions to Free Movement of Persons in the Time of COVID-19” (2023) 14 *European Journal of Risk Regulation* 141; *European Commission* (n 7) 31.

<sup>138</sup> *Meadows v Minister for Justice, Equality and Law Reform* (2010) IESC 3. This test of proportionality should not be confused with the proportionality test used in Constitutional Law as a basis for challenging primary legislation.

<sup>139</sup> For further analysis on proportionality review in Irish administrative law, see DG Morgan, GW Hogan and P Daly, *Administrative Law in Ireland* (Fourth edition, Round Hall, Thomson Reuters 2010). For an analysis of the relationship between proportionality and reasonableness in the case law of the CJEU, see Keyaerts (n 131).

<sup>140</sup> For further analysis see Renn (n 5).



instance, distributional considerations (eg what would be the long-term impact of school closures on future generations?) and countervailing risks (eg risk–risk trade-offs) have an important role in deciding which options to adopt. While these considerations are often neglected when applying the precautionary principle, they are constituents of an impact assessment.

The trend towards a potential union between impact assessment and the precautionary principle began before 2020 in the EU. Using the Irish experience of school closures during the Covid-19 pandemic as a case study, this article has highlighted the essentiality of that trend, in particular when fundamental rights are at stake. Notwithstanding the degree of uncertainty that characterises our “multi-risk world,” one trend is certain: regulatory failures have a propensity to accelerate regulatory reforms. In this sense, one can be hopeful that the post-pandemic era will be characterised by a more evidence-based approach to precaution.

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