



# The precautionary principle and genetically modified organisms: A bone of contention between European institutions and member states

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## ABSTRACT

This manuscript examines how the Precautionary Principle has been applied to provide a mechanism for protection of the environment and health in response to the introduction of Genetically Modified Organisms (GMOs) in Europe. It discusses how the Court of Justice of the European Union (CJEU) handled national requests across four cases in which Member States had failed in their attempt to trigger the Precautionary Principle in order to uphold a ban or suspension of the cultivation or sale of GMOs in their territory. The analysis of these judgements suggests that the court has applied a narrow interpretation to the scientific evidence emerging from risk assessments, and has thereby limited the potential for precautionary measures by Member States to be upheld by the court. This outcome reflects a ‘weak’ application of the Precautionary Principle by the

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court in contrast with the ‘moderate’ formulation and ‘strong’ interpretation of the principle offered by the European legal framework. Moreover, the analysis highlights that the CJEU’s rulings are not keeping pace with the development of the European normative framework which considers the Precautionary Principle as a key tenet and, through the 2015 Directive, enables Member States to ban GMO cultivation without referring to scientific evidence.

**KEYWORDS:** European regulation of genetically modified organisms, AgTech, Precautionary Principle, the 2003 Monsanto Italy case, the 2007 Austrian case, the 2011 France Monsanto case, the 2017 Fidenato case

## INTRODUCTION

The growing global population faces many challenges arising from human activities on the environment, including climate change, loss of biodiversity and food security. Genetically Modified Organisms (GMOs), which are the result of the use of technology in agriculture (AgTech), represent a prime example of an attempt to address such issues through scientific innovation. A GMO is defined under the European framework<sup>1</sup> as any organism whose genetic material has been artificially altered, which can be achieved through several techniques to create hybrid organisms or genetic engineering.<sup>2</sup> Trading GMOs can present significant economic opportunities for both developed and developing countries<sup>3</sup> and, simultaneously, GMOs are viewed by some as a risk for human health and the environment.<sup>4</sup> Indeed, although there is a lack of unequivocal scientific evidence,<sup>5</sup> numerous studies suggest that GMO usage can lead to serious side effects

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- 1 *Directive 2001/18/EC* defines a Genetically Modified Organism as ‘an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination’: See *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms* and repealing *Council Directive 90/220/EEC [2001] OJ L 106/1, 2[2]* (*‘the 2001 Directive’*).
  - 2 See ‘Science and History of GMOs and Other Food Modification Processes’ (U.S. Food & Drug Administration, 2020) <<https://www.fda.gov/food/agricultural-biotechnology/science-and-history-gmos-and-other-food-modification-processes>>; National Research Council (US) Committee, ‘Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health’ (National Academies Press, 2004).
  - 3 ‘Brief 53: Global Status of Commercialized Biotech/GM Crops in 2017: Biotech Crop Adoption Surges as Economic Benefits Accumulate in 22 Years’, ISAAA (Web Page) 8 <<https://www.isaaa.org/resources/publications/briefs/53/download/isaaa-brief-53-2017.pdf>>.
  - 4 MARIA WEIMER, *RISK REGULATION IN THE INTERNAL MARKET: LESSONS FROM AGRICULTURAL BIOTECHNOLOGY* (2019).
  - 5 According to part of the scientific community, cultivation and trade of GMOs do not have collateral effects to human health and the environment. Rather, these products might be seen as a means to reduce world hunger and enhance national economies. In this respect see especially, Colestous Juma, *Preventing hunger: Biotechnology is key Preventing hunger: Change economic policy*, 479 *NATURE* 1–2 (2012); Elisa Pellegrino et al., *Impact of genetically engineered maize on agronomic, environmental and toxicological traits: A meta-analysis of 21 years of field data*, 8 *SCI. REP.* 1–12 (2018); Frank Tenente, *Feeding the World One Seed at a Time: A Practical Alternative for Solving World Hunger*, 5 *NW. UNIV. J. INT’L HUM. RTS.* 298 (2007).

for health and the environment, such as food allergies, decreased nutritional value, increased toxicity and antibiotic resistance.<sup>6</sup>

In the context of GMOs, the Precautionary Principle would aim to minimise the potentially harmful effects on the environment and human health, while balancing potential benefits to agriculture and trade. This manuscript aims to improve understanding of the manner in which the Precautionary Principle is applied in the adjudication of legal disputes in relation to GMOs. This investigation is particularly pertinent and topical considering that legal research is in short supply in the rapidly evolving field of GMOs.<sup>7</sup> As Peel observed, however, ‘many questions regarding the application of the Precautionary Principle in practice are context-dependent’,<sup>8</sup> which invites fuller exposition of the context for this study, which focuses on the European legislation and case-law concerning GMOs.

**Part I** will briefly review the concept of the Precautionary Principle. It will set out the evolution of the principle in the European legal framework as well as in the case-law of the CJEU. Then, it will focus on the *core* elements of the Precautionary Principle and its relationship with scientific uncertainty. In conclusion, the first Part will situate the role of the Precautionary Principle within the European framework.

**Part II** will set out the European legal framework governing GMOs. This investigation will focus on the recent amendments carried by the introduction of the Directive (EU) 2015/412 (the 2015 Directive)<sup>9</sup> and Directive (EU) 2018/350 (the 2018 Directive).<sup>10</sup> The Part will then turn to the three legal mechanisms (i.e. ‘safeguard clauses’, ‘derogation from a harmonisation measure’ and ‘emergency measures’) by means of which Member States have sought to trigger a precautionary response to control the cultivation or sale of GMOs within their territories. This analysis will shed light on some of the key challenges arising from the legal framework and how these might impact on the CJEU in adjudicating disputes relating to GMOs.

**Part III** will carry out a detailed analysis of four key judgments of the CJEU between 2003 and 2017: *Monsanto Italy*,<sup>11</sup> *Austrian case*,<sup>12</sup> *France Monsanto*,<sup>13</sup> and

6 See, for example, Ania Wieczorek, *Use of Biotechnology in Agriculture—Benefits and Risks*, 3 BIOTECHNOLOGY 1 (2003); Trudy Netherwood et al., *Assessing the Survival of Transgenic Plant DNA in the Human Gastrointestinal Tract*, 22 NAT. BIOTECHNOL. 204–209 (2004); Charles M. Benbrook, *Impacts of Genetically Engineered Crops on Pesticides Use in the U.S.—The First Sixteen Years*, 24 ENVIRON. SCI. EUR. 1 (2012).

7 The UN Report on *Frontiers 2018/19: Emerging Issues of Environmental Concern*, considers GMOs as products which must be further investigated.

8 JACQUELINE PEEL, *THE PRECAUTIONARY PRINCIPLE IN PRACTICE: ENVIRONMENTAL DECISION-MAKING AND SCIENTIFIC UNCERTAINTY* 6 (2005).

9 *Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory*, [2001] OJ L 68/1 (‘the 2015 Directive’).

10 *Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms* [2018] OJ L 67/30, (‘The 2018 Directive’).

11 *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others*, C-236/01, EU:C:2003:431 (‘Monsanto Italy’).

12 *Land Oberösterreich and Republic of Austria v Commission of the European Communities*, C-439/05 P and C-454/05 P, EU:C:2007:510 (‘Austrian case’).

13 *Monsanto SAS et al. v Ministre de l’Agriculture et de la Pêche*, C-58/10 to C-68/10, EU:C:2011:553 (‘France Monsanto’).

*Fidenato case*.<sup>14</sup> Their examination will improve understanding of the national and judicial interpretation of the current state of the law on the regulation of GMOs in Europe.<sup>15</sup> From this analysis, it will be possible to draw conclusions about how a narrow approach by the CJEU to scientific evidence emerging from risk assessments can pre-empt the application of the Precautionary Principle during the subsequent risk management stage, highlighting procedural and normative shortfalls in the legal framework governing GMOs in Europe.

Final conclusions will set out key findings that emerge from the analysis of the European normative framework and across the four cases. It will provide some further critical reflections on implications of these findings on the regulation of GMOs in Europe, highlighting also directions for research.

## PART I – THE PRECAUTIONARY PRINCIPLE IN EU LAW

### The Precautionary Principle in the European Legal Framework

Under the European legal framework, Article 191(2) (ex Article 174(2) TEC) of the Treaty on the Functioning of the European Union (TFEU) refers to ‘the Precautionary Principle’ highlighting that ‘Union policy on the environment shall aim at a high level of protection [and] shall be based on the Precautionary Principle (. . .)’.<sup>16</sup> Importantly, the EU has been at the forefront of implementing this principle in different areas. For instance, Article 7 of Regulation No 178/2002 (the 2002 Regulation), which has been taken into account by the CJEU in *Fidenato*, defines the Precautionary Principle in the area of food law.<sup>17</sup>

The Communication from the Commission on the Precautionary Principle (COMM(2000)) reinforces the Precautionary Principle as a key concept of the European legal framework and, more importantly, sets a precautionary approach as the starting point for all European regulations affecting health and the environment.<sup>18</sup> It states:

[W] here scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are *reasonable grounds* for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.<sup>19</sup>

Recourse to the Precautionary Principle is seen as ‘a central plank of Community policy.’<sup>20</sup> The European precautionary policy also emerges clearly from European Directives and Regulations regulating the introduction of GMOs on the European market. Among others, the 2001 Directive, on the release into the environment of

14 *Giorgio Fidenato and Others*, C-111/16, EU:C:2017:676 (*‘Fidenato case’*).

15 This Part will only address those aspects of the cases which are relevant for the purposes of this investigation.

16 Art 191(2) TFEU.

17 *Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the EFSA and laying down procedures in matters of food safety* [2002] OJ L 31/1, Art 7 (*‘the 2002 Regulation’*).

18 *Communication from the Commission on the precautionary principle*, COMM(2000) 1 final (2 February 2000), p 12 para 3 (*‘COMM (2000)’*).

19 *Id.* pp 9–10 (emphasis added).

20 *Id. supra* note 18.

GMOs aims, inter alia, 'to protect human health and the environment . . . [i]n accordance with the precautionary principle.'<sup>21</sup> The 2015 Directive adds also that '[t]he precautionary principle should always be taken into account in the framework of Directive 2001/18/EC and its subsequent implementation.'<sup>22</sup>

Although the COMM(2000) has not made satisfactory progress in clarifying the Precautionary Principle further, failing even to answer many questions about its meaning, its reference to *reasonable grounds* suggests a 'moderate' formulation of the principle.<sup>23</sup> This is particularly interesting considering that the interpretation of the Precautionary Principle.

commonly refers to two broad categories: 'strong' and 'weak'. In short, a 'strong' formulation is prescriptive and favours intervention to prevent potentially harmful activities, with the onus placed on the proponent of an activity to alleviate uncertainty about the nature or extent of associated risks.<sup>24</sup> In contrast, a 'weak' formulation advocates intervention only in cases where a high threshold of evidence for potential harm (e.g. serious or irreversible) is available, leaving intervention as an option and not a requirement.<sup>25</sup> It is not uncommon to find critiques in the literature of a sharp distinction between 'weak and toothless' and 'strong but unreasonable' formulations of the principle.<sup>26</sup> As such, the COMM(2000) provides a *reasonable-moderate* alternative.

Further, the COMM(2000) suggests ways to improve the understanding of this principle in Europe. Specifically, it proposes that the Precautionary Principle should be examined not only in legislative texts, but also in the case law of the CJEU and the Court of First Instance (CFI) since 'they have already had occasion to review the application of the precautionary principle ( . . . ) develop (ing) case law in this area.'<sup>27</sup> These European Courts have, therefore, the power to fill, to a certain extent, that policy vacuum. In light of this, the following section provides an overview of the Precautionary Principle in the case-law of the CJEU.

21 The 2001 Directive, *supra* note 1, art 1. See also, Recital and Art 4.

22 The 2015 Directive, *supra* note 9, Rec 2.

23 See in this regard Kenisha Garnett & David J. Parsons, *Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law*, 37 RISK ANAL. 502–516 (2017).

24 The *Wingspread Statement* provides an example of a 'strong' interpretation of the Precautionary Principle as it suggests the adoption of precautionary measures '[w]hen an activity raises *threats* of harm to human health or the environment': Steven G. Gilbert, 'Precautionary Principle—The Wingspread Statement' on Toxipedia—connecting science and people (1 December 2010, updated by Maria Mergel 16 March 2016) (emphasis added).

25 For example, Article 15 of the *Rio Declaration* refers to 'precautionary measures' and it is described as tending towards a 'weak' version of the Precautionary Principle insofar as it qualifies the requirement to apply the principle depending on the capacity of a State to do so, as well as by factoring in the cost-effectiveness of a precautionary measure. *Rio Declaration on Environment and Development*, 14 June 1992, 31 ILM 874 (1992), Principle 15 ('*Rio Declaration*').

26 DANIEL STEEL, *PHILOSOPHY AND THE PRECAUTIONARY PRINCIPLE: SCIENCE, EVIDENCE, AND ENVIRONMENTAL POLICY* 20 (2015). See also R. Powell, *What's the Harm?: An Evolutionary Theoretical Critique of the Precautionary Principle*, 20 KENNEDY INST. ETHICS J. 181 (2010). H. Sterling Burnett, *Understanding the Precautionary Principle and its Threat to Human Welfare*, 26 SOC. PHILOS. POLICY 378 (2009). Ed Soule, *The Precautionary Principle and the Regulation of US Food and Drug Safety*, 29 J. MED. PHILOS. 333 (2004).

27 COMM(2000), *supra* note 18, p 9.

### The Precautionary Principle in the Case-Law of the CJEU

Spanning from 1983 to 2018, a copious number of European decisions mirror how the interpretation and application of the Precautionary Principle have evolved in the jurisprudential path of the CJEU.<sup>28</sup>

The 1983 *Sandoz* case, represents the first case in which the CJEU recognizes the idea underlying the Precautionary Principle by stating that ‘in so far as there are uncertainties at the present state of scientific research it is for the Member States, in the absence of harmonization, to decide what degree of protection of the health and life of humans they intend to assure.’<sup>29</sup> Subsequent precautionary approaches were taken by the CJEU in the 1984 *Heijn* and 1986 *Mirepoix* decisions.<sup>30</sup> In both cases, the court justifies the implementation of measures aiming to protect public health despite the lack of scientific certainties. One decade later, the CJEU in the 1998 *UK v Commission* case remarks that the adoption of protective measures under the European legal framework disregards the presence of full evidence.<sup>31</sup>

Thus, even without referring explicitly to the principle, the CJEU has constantly supported the adoption of a precautionary approach to safeguard human health and/or the environment.<sup>32</sup> It is only with the 2000 *Greenpeace France and Others* case that the court, for the first time, refers *expressis verbis* to the Precautionary Principle.<sup>33</sup> Since then, judicial references to the Precautionary Principle shape and develop the interpretation of the principle at the European level. In this respect, the 2002 *Pfizer* case represents a milestone. The reasoning given by the CJEU in this case sheds light on a number of aspects concerning the interpretation and application of such principle. It clarifies that in situations of scientific uncertainty in which the Precautionary Principle is applied, risk assessments should not necessarily show the reality of the risk and the seriousness of the potential adverse effects.<sup>34</sup>

Also, the 2002 *Artegodan and Others v Commission* case points out, interestingly, ‘the binding nature of that principle.’<sup>35</sup> In 2002 *Alpharma v Council*, the court emphasises that ‘when the precautionary principle is applied, it may prove impossible to carry out

28 In this respect, see especially, E SCOTFORD, ENVIRONMENTAL PRINCIPLES AND THE EVOLUTION OF ENVIRONMENTAL LAW 166 (2017).

29 *Sandoz BV*, C-174/82, EU:C:1983:213, para 16 (*Sandoz*). The court refers to precaution by recalling the *Frans-Nederlandse Maatschappij voor Biologische Producten*, C-272/80, EU:C:1981:312.

30 *Heijn*, C-94/83, EU:C:1984:285; *Ministère public v Mirepoix*, C-54/85, EU:C:1986:123 (*Mirepoix*).

31 *UK v Commission*, C-180/96, EU:C:1998:192, para 99. See also *The Queen v Ministry of Agriculture*, C-157/96, EU:C:1998:191.

32 Implicit references to the precautionary principle can be found also in *Fedesa and Others*, C-331/88, EU:C:1990:391; *Mondiet v Armement Islais SARL*, C-405/92, EU:C:1993:906; *Association pour la Protection des Animaux Sauvages and Others and Préfet*, C-435/92, EU:C:1994:67 (*ASAP*); *Spain v Council*, C-61/96, C-132/97, C-45/98, C-27/99, C-81/00 and C-22/01, EU:C:2002:230.

33 *Greenpeace France and Others*, Case C-6/99, EU:C:2000:148, paras 6, 19, 35, 40, and 44. Four months after this decision, the court mentions explicitly the principle also in *Bergaderm and Goupil v Commission*, C-352/98 P, EU:C:2000:361, paras 32 and 52 (*‘Bergaderm’*).

34 *Pfizer Animal Health v Council*, T-13/99, EU:T:2002:209, para 142 (*‘Pfizer’*).

35 *Artegodan and Others v Commission*, T 74/00, T 76/00, T 83/00 to T 85/00, T 132/00, T 137/00 and T 141/00, EU:T:2002:283, para 182. See also paras 183 and 184.



a full risk assessment . . . because of the inadequate nature of the available scientific data.<sup>36</sup>

In 2003, the CJEU in *Monsanto Italy* addresses, inter alia, the question whether, in light of the Precautionary Principle, a Member State could adopt safeguard measures suspending the trade in or use of GMOs within its territory according to Article 12 of Regulation (EC) No 258/97.<sup>37</sup> Despite the court acknowledges that ‘the safeguard clause must be understood as giving specific expression to the Precautionary Principle’,<sup>38</sup> the CJEU ruled that in this case the national evidence did not reveal a *necessity* to implement safeguard measures in light of the Precautionary Principle, thereby setting the bar for proving risk closer to a standard of ‘real’ than ‘hypothetical’.<sup>39</sup> In the 2011 *France Monsanto* case, the court addresses the additional question whether emergency measures of Article 34 of the Regulation No 1829/2003 (the 2003 Regulation) can be adopted in light of the Precautionary Principle.<sup>40</sup> How the court dealt with this national question is developed below in addressing the analysis of the *Fidenato* case.

In alignment with its previous case-law, the CJEU in the 2018 *Bayer CropScience v Commission* case remarks that the adoption or protective measure in light of the Precautionary Principle ‘cannot be made subject to proof of the lack of any risk, in so far as such proof is generally impossible to give in scientific terms since zero risk does not exist in practice.’<sup>41</sup> Nevertheless, the ongoing debate on the interpretation of risk and the scientific uncertainty surrounding potentially adverse effects of GMOs on human health<sup>42</sup> and the environment<sup>43</sup> challenge the capacity of the CJEU to operationalise the Precautionary Principle in the field of GMOs. The following section explores the *core* elements of the Precautionary Principle and its relationship with scientific uncertainty.

36 *Alpharma v Council*, T-70/99, EU:T:2002:210, para 173. See also the reasoning given by the court in *Solvay Pharmaceuticals v Council*, T-392/02, EU:T:2003:277, para 121.

37 *Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1991 concerning novel foods and novel food ingredients* [1997] OJ L 43/1, art 12 (‘Novel Foods Regulation’).

38 *Monsanto Italy*, *supra* note 11, at para 110.

39 Ruby R. Fernandez, *Monsanto and the Requirement for Real Risks in GM Food Regulation*, 335 *LOYOLA LOS ANGELES INT. COMP. LAW REV.* 335, 338 (2006). See also *Commission v Denmark*, C 192/01, EU:C:2003:492; *Commission v France*, C-496/01, EU:C:2004:137.

40 *France Monsanto*, *supra* note 13, at para 38. *Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed*, [2003] OJ L 268/1 18.10.03, art 34 (‘the 2003 Regulation’).

41 *Bayer CropScience v Commission*, T-429/13 and T-451/13, EU:T:2018:280, para 116 (Bayer).

42 Sean A. Weaver & Michael C. Morris, *Risks associated with genetic modification: An annotated bibliography of peer reviewed natural science publications*, 18 *J. AGRIC. ENVIRON. ETHICS* 157–189 (2005); S. M. Martin-Orue et al., *Degradation of Transgenic DNA From Genetically Modified Soya and Maize in Human Intestinal Simulations*, 87 *BR. J. NUTR.* 533–542 (2002); Ruchir Raman, *The impact of Genetically Modified (GM) crops in modern agriculture: A review*, 8 *GM CROP. FOOD* 195–208 (2017).

43 Shobha Sondhia, *Herbicide residue hazards and their mitigation modalities*, in *BIENNIAL CONFERENCE OF THE INDIAN SOCIETY OF WEED SCIENCE ON “DOUBLING FARMERS’ INCOME BY 2022: THE ROLE OF WEED SCIENCE”* 21–22 (2017); William M. Muir, *The Threats and Benefits of GM Fish*, 5 *EUR. MOL. BIOL. ORGAN.* 654 (2004); William M. Muir & Richard D. Howard, *Assessment of Possible Ecological Risks and Hazards of Transgenic Fish with Implications for Other Sexually Reproducing Organisms*, 11 *TRANSGENIC RES.* 101 (2002).

### The core elements of the Precautionary Principle and its Relationship with Scientific Uncertainty

Despite the ongoing debate over formulation, role, and interpretation of this principle,<sup>44</sup> the *core* elements of the Precautionary Principle are relatively clear: (a) existence of *risk* perceived as a threat of harm; (b) presence of scientific *uncertainty* regarding potential effects; and (c) corresponding *action* by stakeholders.<sup>45</sup>

The Precautionary Principle is intrinsically linked to risk. Only a potentially hazardous—although not merely hypothetical—situation can justify the triggering of precautionary measures. As clarified by the CJEU, while *risk* ‘constitutes the degree of probability that the acceptance of certain measures or practices will adversely affect the interests safeguarded by the legal order’, *hazard* (or *danger*) ‘is commonly used in a broader sense and describes any product or procedure capable of having an adverse effect on human health or any other interest safeguarded by the legal order.’<sup>46</sup>

It merits noting that, like ‘risk’, what constitutes an ‘adverse effect’ will vary on a subjective level,<sup>47</sup> such as whether it is perceived by a typical consumer, environmental activist or advocate for a multinational producer.

The concept of risk assumes a crucial role in ‘risk governance’, which Renn has described as a process of integrating the points of view of various actors and different aspects of risk (scientific, economic, societal and cultural) in order to carry out effective collective decision-making.<sup>48</sup> Drawing upon concepts in natural science, risk governance has three main components: risk assessment, risk management and risk communication.<sup>49</sup> Under the EU framework, this three-stage process is referred to as ‘risk analysis’.

The first phase of risk analysis (i.e. ‘risk assessment’) is located mainly in the scientific domain and defined ‘as a tool of gaining knowledge about risks.’<sup>50</sup> The aim in this phase is to quantify and evaluate the probabilities of possible outcomes,<sup>51</sup> providing a mechanism to deal with systemic risks facing society.<sup>52</sup> Various authors have voiced their dissatisfaction with this approach: noting that the main objective of the ‘risk assessment’ phase is to address the range of ‘uncertainty representations’;<sup>53</sup> arguing that this phase should be ‘solution-focused’, requiring understanding of the

44 For detailed discussions about legal debated surrounding formulation, role, and interpretation of the precautionary principle, see ARIE TROUWBORST, *PRECAUTIONARY RIGHTS AND DUTIES OF STATES* (2006). STEEL, *supra* note 26.

45 Trouwborst states that ‘[t]he three legs of the precautionary tripod, are (1) a threat of harm, (2) uncertainty, and (3) action’: TROUWBORST, *supra* note 44, at 30. See ARIE TROUWBORST, *EVOLUTION AND STATUS OF THE PRECAUTIONARY PRINCIPLE IN INTERNATIONAL LAW* 51–2 (2002).

46 Bayer, *supra* note 41, para 121.

47 Ortwin Renn et al., *Risks*, in *SAFE OR NOT SAFE: DECIDING WHAT RISKS TO ACCEPT IN OUR ENVIRONMENT AND FOOD* 1, 3 (Paul Pechan et al. eds., 2011).

48 *Id.* at 12.

49 *Id.* at 12. See also Anne Ingeborg Myhr & Terje Traavik, *The Precautionary Principle: Scientific Uncertainty and Omitted Research in the Context of GMO Use and Release*, 15 *J. AGRIC. ENVIRON. ETHICS* 73 (2002). PAUL C. STERN & HARVEY V. FINEBERG, *UNDERSTANDING RISK -INFORMING DECISIONS IN A DEMOCRATIC SOCIETY* (1996).

50 Renn and Al, *supra* note 47, at 13.

51 Myhr and Traavik, *supra* note 49, at 74.

52 Didier Bourguignon, ‘The Precautionary Principle—Definitions, Applications and Governance’ (Research Paper No 573.876, European Parliament Think Tank, 2015) <http://www.europarl.europa.eu/thinktank>.

53 Terje Aven, *Foundational Issues in Risk Assessment and Risk Management*, 32 *RISK ANAL.* 1647 (2012).



problem;<sup>54</sup> advocating ‘replacement of risk assessment by the precautionary principle’;<sup>55</sup> criticising risk assessment as ‘part of an advocacy of the strong definition of the precautionary principle’;<sup>56</sup> and expressing concerns about the circumstances under which ‘risk management depends on the knowledge input from risk assessment’.<sup>57</sup>

The second phase of risk analysis (i.e. risk management) involves the balancing of interests through consideration of ‘subjective judgments of the community about the significance of identified risks and the socio-economic factors that influence the prioritisation of different risk problems’.<sup>58</sup>

Finally, the third phase of risk analysis (i.e. risk communication) has been defined as ‘a two-way exchange of information between interested parties about the nature, significance and/or control of a risk’.<sup>59</sup>

Noteworthy, although ‘[t]he precautionary principle should be considered within a structured approach to the analysis of risk’,<sup>60</sup> the COMM(2000) underlines that the principle ‘is particularly relevant to the management of risk’.<sup>61</sup> This approach prescribed under the EU framework aims, at least in theory, to allow a functional evaluation of scientific considerations in the first stage of risk assessment and for societal concerns to be addressed in the second stage of risk management. Nevertheless, according to some scholars this approach prevents the Precautionary Principle from having any useful input into decision-making.<sup>62</sup> Some proponents of GMOs argue to apply the Precautionary Principle at either the risk assessment or risk management stage,<sup>63</sup> while others argue that the Precautionary Principle should only be applied in the risk assessment stage.<sup>64</sup> The phase of ‘risk assessment’ has in fact a crucial role as underlined by the circumstance that ‘risk management depends on the knowledge input from risk assessment’. Thus, since the findings that emerge from risk assessment inform the court’s deliberations in the subsequent risk management stage, it is hard to understand

54 Bernard D. Goldstein, *The Culture of Environmental Health Protection: Risk Assessment, Precautionary Principle, Public Health, and Sustainability*, 17 HUM. ECOL. RISK ASSESS. AN INT. J. 795 (2011).

55 *Id.* at 797. See also Adam M. Finkel, “Solution-Focused Risk Assessment”—A Proposal for the Fusion of *Environmental Analysis and Action*, 17 HUM. ECOL. RISK ASSESS. 754 (2011).

56 Peter Montague, ‘Two Friends Debate Risk Assessment and Precaution’ on Rachel’s Democracy & Health News 920 (16 August 2007) <[http://www.rachel.org/en/newsletters/rachels\\_news/print/920#Two-Friends-Debate-Risk-Assessment-and-Precaution](http://www.rachel.org/en/newsletters/rachels_news/print/920#Two-Friends-Debate-Risk-Assessment-and-Precaution)>. See also Sheldon Krinsky, *The Precautionary Approach*, 13 FORUM APPL. RES. PUBLIC POLICY 34 (1999). Carolyn Raffensperger, Ted Schettler & Nancy Myers, *Precaution: Belief, Regulatory System, and Overarching Principle*, 6 INT. J. OCCUP. ENVIRON. HEALTH 266 (2000). MARY O’BRIEN, MAKING BETTER ENVIRONMENTAL DECISIONS: AN ALTERNATIVE TO RISK ASSESSMENT (2000). Goldstein, *supra* note 54, at 797.

57 Renn and Al, *supra* note 47, at 14.

58 NATIONAL RESEARCH COUNCIL, *RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS* 18–9 (1983). See also PEEL, *supra* note 8, at 146.

59 VT Covello, *Risk communication and occupational medicine*, 35 J. OCCUP. ENVIRON. MED. 18, 18 (1993).

60 COMM(2000), *supra* note 18, p 2 para 4.

61 *Id.* *supra* note 61.

62 See Chauncey Starr, *The Precautionary Principle Versus Risk Analysis*, 23 RISK ANAL. 1, 3 (2003). P Wenneras, *Fog and Acid Rain Drifting From Luxembourg Over Art. 95 (4) EC*, 12 EUR. ENVIRON. LAW REV. 169 (2003). Peter M Chapman, *Does The Precautionary Principle Have A Role in Ecological Risk Assessment?*, 5 HUM. ECOL. RISK ASSESS. AN INT. J. 885 (1999).

63 GARY E. MARCHANT & KENNETH MOSSMAN L., *ARBITRARY AND CAPRICIOUS—THE PRECAUTIONARY PRINCIPLES IN THE EUROPEAN COURTS* 13 (2005).

64 Anne Ingeborg Myhr & Terje Traavik, *The Precautionary Principle Applied to Deliberate Release of Genetically Modified Organisms (GMOs)*, 11 MICROB. ECOL. HEALTH DIS. 65, 73 (1999).

how the Precautionary Principle can affect the second stage of risk management if it is not taken into account in carrying out risk assessment. As such, considering precaution in the first informative phase of risk assessment becomes decisive. It would provide decision-makers with a scenario in which biotechnology risks are assessed against the adoption of precautionary actions. This, in turn, would favour the adoption of well-informed decisions on the management of biotechnology risks. In light of this, adopting precaution in both stages of risk assessment and risk management would be desirable.

As regards the second element of the Precautionary Principle, the COMM (2000) describes scientific uncertainty as follows:

Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen, the measurements made, the samples drawn, the models used and the causal relationship employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data. Uncertainty may relate to qualitative or quantitative elements of the analysis.<sup>65</sup>

The Precautionary Principle does not cover all levels of uncertainty, as a more than hypothetical probability of harm has to be present to trigger precaution. Nevertheless, it encompasses all types of uncertainty.<sup>66</sup> The possibility to trigger the Precautionary Principle also in circumstances where scientific uncertainty still persists does not mean, however, that the employment of precautionary measures disregards scientific considerations. Rather, '[s]cientific considerations lie at the heart of the precautionary principle as it relies on an in-depth assessment of scientific knowledge<sup>67</sup> including any remaining uncertainties.'<sup>68</sup> As Trouwborst observes, 'under the precautionary principle action is not primarily, nor even normally, taken *because* of scientific uncertainty but rather *in spite of* it, and indeed even in its apparent absence.'<sup>69</sup> In other words, precautionary actions of states (i.e. the third element of the principle) do not depend on the presence of scientific uncertainty but on the existence of a threat of harm.

To conclude, this review of the place of the Precautionary Principle in the process of risk analysis under the European framework indicates a highly fragmented source of legal doctrine.<sup>70</sup> Although a significant body of scholarship in this area has approached the issue from a theoretical perspective, there is a gap in critical analysis of the direct and indirect influences on judicial decision-making relating to the Precautionary Principle in the European framework. As indicated by the Commission of the European Communities: 'To understand fully the use of the precautionary principle in the European Union, it is necessary to examine the legislative texts, the case law of the court of Justice (...), and the policy approaches that have emerged.'<sup>71</sup> Whilst this current inquiry

65 COMM(2000), *supra* note 18, at 13–14.

66 ALINE L. JAECKEL, *THE INTERNATIONAL SEABED AUTHORITY AND THE PRECAUTIONARY PRINCIPLE—BALANCING DEEP SEABED MINERAL MINING AND MARINE ENVIRONMENTAL PROTECTION* 38–9 (2017).

67 *Id.* at 36.

68 *Id.* at 36.

69 TROUWBORST, *supra* note 44, at 95.

70 It should be noted that a sizable number of works do not explicitly analyse how the Precautionary Principle affects policy making. Rather, the issues surrounding the principle are addressed through a theoretical lens.

71 COMM(2000), *supra* note 18, p 8(3).

cannot elucidate the full range of scientific, economic and political interests that inform judicial decision-making through a doctrinal research methodology, the analysis in this manuscript should nevertheless improve understanding of how EU policy on GMOs translates (or, alternatively, fails to translate) into to judicial decision-making.

This manuscript may thus also help to shed light on the extent to which EU policy informs the court's decision-making through its consideration of evidence in the risk assessment phase, and whether poorly defined conceptual boundaries may ultimately contribute to inconsistent application of the Precautionary Principle. As the application of the Precautionary Principle is context-dependent, the following Part proceeds by briefly reviewing the evolution of the legal framework specific to GMOs in Europe.

## PART II—REGULATION OF GENETICALLY MODIFIED ORGANISMS AND MECHANISMS TO ADOPT PRECAUTIONARY MEASURES UNDER THE EUROPEAN LEGAL FRAMEWORK

### The Evolution of the European Regulation on GMOs

To date, the current European legislative framework referring to GMOs aspires to:

- Protect human and animal health and the environment by introducing a safety assessment of the highest possible standards at EU level before any GMO is placed on the market;
- Put in place harmonised procedures for risk assessment and authorisation of GMOs; and
- Ensure clear labelling and traceability of GMOs placed on the market.<sup>72</sup>

In order to achieve these goals, Europe has provided as 'building blocks of the GMO legislation'<sup>73</sup> five legislative pillars represented by three European Directives<sup>74</sup> and two European Regulations,<sup>75</sup> and has implemented several rules and recommendations on more specific aspects.<sup>76</sup>

The 2001 Directive,<sup>77</sup> which replaced the previous Directive 90/220 'for reasons of clarity and rationalisation',<sup>78</sup> represents one of the five legislative pillars. Through this Directive, the European legislator expressly set out a normative framework for a

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72 European Commission, 'GMO legislation', [http://ec.europa.eu/food/plant/gmo/legislation/index\\_en.htm](http://ec.europa.eu/food/plant/gmo/legislation/index_en.htm).

73 *Id.*

74 The 2001 Directive, *supra* note 1, art 2(2); the 2015 Directive, *supra* note 9; Directive 2009/41/EC of the European Parliament and the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (recast) [2009] OJ L 125/75.

75 The 2003 Regulation, *supra* note 40; Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [2003] OJ L 268/24.

76 Dennis Eriksson, *Recovering the original intentions of risk assessment and management of genetically modified organisms in the European union*, 6 FRONT. BIOENG. BIOTECHNOL. 1–4, In this respect see (2018); Dennis Eriksson, *The evolving EU regulatory framework for precision breeding*, 132 THEOR. APPL. GENET. 569–573 (2019), <https://doi.org/10.1007/s00122-018-3200-9>.

77 The 2001 Directive, *supra* note 1, art 2(2).

78 *Id. supra* note 1, Recital para 3.

precautionary approach<sup>79</sup> in order to require Member States to take all appropriate measures in order to avoid harmful effects on health and the environment arising from deliberate release of GMOs into the environment or placing GMOs on the market. However, despite the intention of the European Legislator to consider the Precautionary Principle as ‘a central plank of Community policy’,<sup>80</sup> a number of provisions, as demonstrated by their implementation by the CJEU in Part III, effectively serve to impair the Precautionary Principle from achieving its potential under the European regulatory framework.

One sore point of such Directive concerns, for instance, the assessment of products that have already been subjected to prior applications. Recital 17 of the 2001 Directive emphasises that GMOs ‘which have conventionally been used in a number of applications and have a long safety record’<sup>81</sup> are not subject to the application of provisions laid down by the same Directive.<sup>82</sup> This problem for Member States emerges clearly in *France Monsanto*,<sup>83</sup> which will be analysed in Part III, insofar as the European provision conflicts with the CJEU’s request to the Member State to carry out of a risk assessment as completely as possible.

Give the interpretative issues posed by the 2001 Directive and in the face of ongoing public opposition to GMOs, the European normative framework has been recently amended with the introduction of the 2015 Directive and the 2018 Directive, both amending the 2001 Directive.

#### The 2015 Directive: A Critical Analysis

The 2015 Directive represents the first recent attempt to improve the GMOs governance system in Europe. Interestingly, in the first half of 2012, the Danish Government presented a proposal that multinationals could obtain the approval to cultivate their GM crop on European territory and commit in advance not to market them in objecting Member States; if an agreement proved unsuccessful, Member States could still find themselves in a position to argue harmful effects on health or the environment to ban cultivation within their territory. The Danish proposal was not approved, however, and supported by only 20 countries against the qualified majority.<sup>84</sup>

Instead of this negotiated approach, the 2015 Directive introduced a new Article 26-b into the 2001 Directive, which provides ‘the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory’.<sup>85</sup>

It should be noted that the Commission proposed to extend this amendment even for the trade of GMOs. However, the European Parliament contested this proposition,

79 *Id. supra* note 1, art 4(1).

80 COMM(2000), *supra* note 18, at 12.

81 The 2001 Directive, *supra* note 1, Recital para 17.

82 According to art. 23, the reassessment of GM products is allowed only when new scientific knowledge suggest their potential harmful effects.

83 *France Monsanto*, *supra* note 13.

84 P. Christensen, ‘European Council of Ministers Rejects a Proposal to Institutionalize National Bans on GMOs’ on Seed In Context Blog—Commentary on the World of Seed (24 March 2012); JALE TOSUN, RISK REGULATION IN EUROPE ASSESSING THE APPLICATION OF THE PRECAUTIONARY PRINCIPLE 72–3 (2012), papers2://publication/uuid/31104857–6684-4D59-950F-81472F144695.

85 The 2015 Directive, *supra* note 9, art 26-b.

and consequently rejected that proposal because it was deemed to be ‘impracticable’ for its socio-economic impacts.<sup>86</sup>

At first glance, such an amendment would appear to provide a great opportunity for Member States to independently decide whether to cultivate GMOs on their territory and, consequently, the level of precaution to be applied. However, a more critical analysis reveals elements of the amendment that might prevent Member States from taking national decisions concerning the cultivation of GMOs on their territories. Member States are, for instance, not allowed by the 2015 Directive to introduce restrictions based on risks that the EFSA has already assessed. This means, as Geelhoed notes, that ‘Article 26b is not likely to grant Member States full autonomy to protect themselves against the (uncertain) risks for their natural surroundings, . . . if the EFSA’s E [nvironmental] R [isk] A [ssessment] has not at all acknowledged the possibility that they could materialise.’<sup>87</sup>

Further, thorny aspects of the 2015 Directive regard (i) its reference only to the *cultivation* of GMOs, excluding the question of trade (and consequent import) of GMO foodstuffs, and (ii) the vagueness of the provision that ‘Member States should also be allowed to base their measures on . . . *other legitimate factors* including those relating to cultural traditions.’<sup>88</sup>

In light of this, the adoption of the 2015 Directive may have also been motivated by the necessity to appease Member States. Nevertheless, this observation should not overshadow a key aspect carried by the 2015 Directive: The new requirement to justify domestic restrictions or bans on ‘compelling grounds’ does not refer to science-based evidence. In other words, the European States are enabled to impose a ban on GMO crops without providing any scientific evidence in support of their positions. This, in turn, leaves room for the consideration of other interests related to the social impact of GMOs.

In addition to article 26-b, the 2015 Directive added a new paragraph ‘1a’ to Article 26a of the 2001 Directive, providing that ‘[a] s from 3 April 2017 Member States in which GMOs are cultivated shall take appropriate measures in border areas of their territory with the aim of avoiding possible cross-border contamination into neighbouring Member States in which the cultivation of those GMOs is prohibited, unless such measures are unnecessary in the light of particular geographical conditions. Those measures shall be communicated to the Commission.’<sup>89</sup> This provision should be read along with Recommendation C-200/1, according to which Member States can adopt measures to exclude GMO cultivation from large areas (*GM-free areas*) whether proportionate to the objective pursued (i.e. protection of particular needs of conventional and/or organic farming) and in accordance with the subsidiarity principle.<sup>90</sup> Thus, the issue

86 European Parliament, Report on the proposal for a Regulation of the European Parliament and of the Council Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory (COM(2010)0375—C7-0178/2010-2010/0208(COD)) A7-0170/2011. Strasbourg: European Parliament, at p. 17.

87 Miranda Geelhoed, *Divided in Diversity: Reforming the EU’s GMO Regime*, 18 CAMBRIDGE YEARB. EUR. LEG. STUD. 20–44, 43–4 (2016).

88 The 2015 Directive, *supra* note 9, Recital 15 (emphasis added).

89 *Id.* art 1 (1).

90 *Commission Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops* [2010] OJ 2010/C 200/01, at para 2.4.

of cross-border contamination is expected to be at the centre of attention for years to come.

To conclude, despite some normative limits, it must be recognised that Article 26-b of the 2015 Directive grants Member States more (though not full) autonomy in deciding whether measures restricting or banning the cultivation of GMOs on their territory must be implemented on their territory.

### The 2018 Directive: A step towards a better understanding of risk assessment and GMOs?

The 2018 Directive entered into force on 29 March 2018 amending, among others, Annexes II of the 2001 Directive.<sup>91</sup> The latter sets out requirements for the environmental risk assessment (ERA) of GMOs which the 2018 Directive has partially amended or enriched with the introduction of new sections into the 2001 Directive. A noteworthy amendment is the introduction of the new section C.1, which now requires ERA to identify ‘the *intended* and *unintended* changes resulting from the genetic modification and [to] evaluate their potential to cause adverse effects on human health and on the environment.’<sup>92</sup> Additionally, *long-term adverse effects* of a GMO, that is ‘effects resulting either from a delayed response by organisms or their progeny to long-term or chronic exposure to a GMO or from an extensive use of a GMO in time and space’,<sup>93</sup> must be considered in the ERA along with *cumulative long-term adverse effects* of GMOs on human health and the environment. The latter require ‘tak [ing] into account the GMOs deliberately released or placed on the market in the past.’<sup>94</sup> Before the 2018 amendments, Annex II provided only a brief and vague description of the ‘cumulative long-term effects.’<sup>95</sup>

In line with the new requirement to assess cumulative long-term effects, the amended section C.2 imposes the obligation to take account of ‘[r]elevant information from previous releases of the same or similar GMOs and organisms with similar traits.’<sup>96</sup> Interestingly, the 2001 Directive merely invited to consider this ‘relevant information.’<sup>97</sup>

The introduction of section C.1 to Annex II can be conceived as a step towards a greater awareness about the complexity surrounding the assessment of GMOs, which requires to be addressed by taking account of intended and unintended changes as well as long-term and cumulative long-term effects.

A further relevant amendment concerns the section of Annex II on steps in the ERA, which has been enriched with more requirements for carrying out risk assessment. The description of hazard characterization, referring to the ‘magnitude of each potential adverse effect’, in the text of the amended Directive ‘shall’—rather than the

91 The 2018 Directive also amended Annex III, Annex IIIB, and Annex IV of the 2001 Directive. However, for the purposes of the present analysis, it is sufficient to shed light only on the amendment of Annex II. The 2018 Directive, *supra* note 10.

92 *Id.* Annex II, C.1 para 1.

93 *Id.* *supra* note 10, para 2.

94 *Id.* *supra* note 10.

95 The 2001 Directive, *supra* note 1, Annex II, para 1.

96 The amended text requires that this relevant information ‘shall be considered in the e.r.a.’: The 2018 Directive, *supra* note 10, Annex II, C.2.

97 Before the 2018 amendments, Annex II, section C.1 of the 2001 Directive established that relevant information ‘can’ be taken into account. *Id.* *supra* note 10.



less compulsory 'should' previously adopted—be evaluated.<sup>98</sup> Also, where possible, the characterization of hazard, exposure, and risk must be expressed in *quantitative* terms.<sup>99</sup> Accordingly, '[t]he risk management strategies shall be described in terms of reducing the hazard or the exposure' with a *quantification* of risk reduction.<sup>100</sup> Where it is not possible to carry out a quantifiable evaluation of hazard, exposure, and risk, the 2018 Directive requires their qualitative evaluation expressed through the categories of 'high', 'moderate', 'low', and 'negligible'.<sup>101</sup> Finally, the overall assessment of risk is required through a '*qualitative* and, where possible, *quantitative* evaluation'.<sup>102</sup>

The use of words such as 'shall' in considering the magnitude of each potential adverse effects, highlights a further step towards a keener understanding of the complexity surrounding GMOs. However, the same cannot be claimed for the acknowledgement of a *quantitative* evaluation of risk as the preferable approach to assessing GMOs.<sup>103</sup> One could argue that the adoption of a quantitative approach to risk is not surprising given that risk is commonly described as the product of the following mathematical formula:

$$\text{Risk} = \text{gravity} \times \text{probability of harm}^{104}.$$

Nevertheless, this quantifiable definition does not leave room for the consideration of the emerging social function of risk.<sup>105</sup> In this respect, Thayyil argues that a deep understanding of risk in the regulation of technology can be achieved only by examining sociological conceptualizations of risk.<sup>106</sup> Thus, by requiring a quantitative evaluation of risk, the 2018 Directive falls short of a sophisticated regulation capable of capturing the high degree of complexity surrounding the assessment of GMOs, which would require a qualitative evaluation of related adverse effects. Qualitative assessments are recommended as they adopt techniques considering both scientific and social discourses concerning GMOs.<sup>107</sup> This, in turn, includes an assessment of the social acceptability of uncertain risks concerning GMOs, which is highly

98 *Id. supra* note 10, Annex II, C.2 para 2.

99 *Id. supra* note 10, paras 2, 3, 4.

100 *Id. supra* note 10, para 5.

101 *Id. supra* note 10, paras 2, 3, 4.

102 *Id. supra* note 10, para 6 (emphasis added). The Annex II before the 2018 amendment did not refer explicitly to both quantitative and qualitative assessment. Some reference to quantitative issues were outlined in Annex IIIA paras IIA(7), IIC(g), IIIA(6).

103 The 2018 Directive stresses that a qualitative assessment is required only in the final stage of the overall risk evaluation and conclusions. The 2018 Directive, *supra* note 10, para 6.

104 CATHERINE ALTHAUS, CALCULATING POLITICAL RISK 20–3 (2008). See also TROUWBORST, *supra* note 44, at 26–9. Renn and Al, *supra* note 47, at 3.

105 In this respect, see E. Donald Elliot, *Risk and Culture: An Essay on the Selection of Technological and Environmental Dangers*, 12 YALE LAW SCH. LEG. SCHOLARSH. REPOS. FAC. 414 (1983). Steve Rayner, *Cultural Theory and Risk Analysis*, in SOCIAL THEORIES OF RISK 53–79, 83–116 (S. Krimsky & D. Goldin eds., 1992). Scott Lash, *Risk Culture*, in THE RISK SOCIETY AND BEYOND: CRITICAL ISSUES FOR SOCIAL THEORY 47–62, 47–62 (B. Adam, U. Beck, & J. Van Loon eds., 2000). Alan Scott, *Risk Society or Angst Society: Two Views of Risk, Consciousness and Community*, in THE RISK SOCIETY AND BEYOND: CRITICAL ISSUES FOR SOCIAL THEORY 33–46, 33–46 (B. Adam, U. Beck, & J. Van Loon eds., 2000).

106 NAVEEN THAYYIL, BIOTECHNOLOGY REGULATION AND GMOs—LAW, TECHNOLOGY AND PUBLIC CONTESTATIONS IN EUROPE 64 (2014).

107 Keith R. Hayes, *Best practice and current practice in ecological risk assessment for genetically modified organisms*, CSIRO Div. MAR. RES. (2004).

relevant considering that the complexity of GMOs cannot be reduced to a scientific matter.

By taking some steps forward and others back, the amendments introduced by the 2018 Directive do not advance considerably the European regulatory framework towards an ERA more capable to evaluate the complexity surrounding GMOs.

Against this normative framework disciplining the regulation of GMOs in Europe, the next section highlights the mechanisms through which Member States triggered the Precautionary Principle in the four cases analysed in Part III.

### **Mechanisms for Member States to Take Precautionary Measures in relation to Genetically Modified Organisms**

The European framework provides Member States with different mechanisms to adopt precautionary measures relating to GMOs in line with EU policy. The four cases analysed in Part III examine how Member States have sought to apply a precautionary approach to ban the cultivation or trade of GMOs in their territory by applying three different measures:

- A ‘safeguard clause’, invoked in *Monsanto Italy* and *France Monsanto*, drawing upon two distinct legal instruments: Article 12 of Regulation No 258/97 (Novel Foods Regulation)<sup>108</sup> and Article 23 of the 2001 Directive;<sup>109</sup>
- A ‘derogation from a harmonisation measure’, employed in the *Austrian case*, based on Article 95(5) of the *EC Treaty*; and
- An ‘emergency measure’, applied in *France Monsanto* and in *Fidenato case* under Article 34 of the 2003 Regulation.<sup>110</sup>

#### *‘Safeguard Clauses’: Article 12 Regulation No 258/97/EC and Article 23 of the 2001 Directive*

Under the European framework, Member States can adopt different mechanisms to implement precautionary measures relating to GMOs.<sup>111</sup> Both Italy and France invoked a ‘safeguard clause’ drawing upon, respectively, Article 12 of Regulation No 258/97<sup>112</sup> and Article 23 of the 2001 Directive.<sup>113</sup>

The applicant in *Monsanto Italy* relied on Regulation No 258/97, which concerns novel foods and novel food ingredients in the European market. Article 12 of the 1997 Regulation allows a Member State to restrict or prohibit the trade in or use of GMOs within its territory if it has ‘detailed grounds’ to consider that a food or food ingredient

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108 Novel Foods Regulation, *supra* note 37, art 12.

109 The 2001 Directive, *supra* note 1, art 23.

110 The 2003 Regulation, *supra* note 40, art 34.

111 Other general measures can be adopted to invoke the Precautionary Principle. Nevertheless, this manuscript will limit discussion to only those mechanisms considered by the CJEU in the judgments analysed in Part III.

112 Novel Foods Regulation, *supra* note 37, art 12.

113 In addition, the applicant in *France Monsanto* invoked an ‘emergency measure’ pursuant to Article 34 of the 2003 Regulation.

‘endangers human health or the environment.’<sup>114</sup> This view can arise from either ‘new information or a reassessment of existing information.’<sup>115</sup>

This Regulation refers to the assessment of substantial equivalence between new foodstuffs and existing foods or food ingredients on the basis of either: available and generally recognised scientific evidence; or, an opinion delivered by one of the food assessment bodies of the Member State responsible for preparing the initial assessment report.<sup>116</sup> The parameters to carry out such evaluation include reference to ‘their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.’<sup>117</sup> However, as suggested by Advocate General A.G. Alber in his opinion regarding *Monsanto Italy*, these criteria to establish the substantial equivalence of GM foods are not suitable for the purpose of determining whether they present some risk to human health.<sup>118</sup>

It should be noted that, in 2013, the European Commission presented a proposal for a more efficient authorisation procedure to place novel foods on the European market without compromising a high level of public health.<sup>119</sup> Thus, on 25 November 2015, the European Parliament and Council approved Regulation (EU) 2015/2283, which repealed and replaced Regulation (EC) No 258/97.<sup>120</sup> Interestingly, despite current gaps in scientific knowledge on benefits and effects of GMOs, the new Regulation stressed that ‘[n]ew technologies and innovations in food production should be encouraged as they could reduce the environmental impact of food production, enhance food security and bring benefits to consumers as long as the high level of consumer protection is ensured.’<sup>121</sup>

The applicant in *France Monsanto*<sup>122</sup> relied instead on the 2001 Directive concerning the deliberate release of GMOs into the environment.<sup>123</sup> Article 23 of that Directive, applied in *France Monsanto*,<sup>124</sup> allows a Member State to provisionally restrict or prohibit the use or sale of GMOs in its territory if it considers ‘on detailed grounds’ that a product constitutes ‘a risk to human health or the environment.’<sup>125</sup> Procedurally, the State can take this action only in cases where a product has gone through the notification procedure and received consent to be placed on the market under the Directive.<sup>126</sup> The view to restrict or prohibit the product must be as a result of either: ‘new or

114 *Id. supra* note 37, Article 12

115 *Id. supra* note 37.

116 According to Article 1(2), there are six categories of novel foods and food ingredients to which the provisions of Regulation 258/97 apply.

117 Novel Foods Regulation, *supra* note 37, art 3 (4).

118 *Opinion of Advocate General Alber (C-236/01) [2003] ECR I-8110, I-63-73.*

119 European Commission, Proposal for a Regulation of the European Parliament and of the Council on novel foods COM(2013) 894 final 2013/0435.

120 *Regulation (EU) 2015/2283 of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 [2015] OJ L 327/1 (‘Novel Foods Regulation 2015’).*

121 *Id.* Recital at para 29.

122 *France Monsanto*, *supra* note 13.

123 The 2001 Directive, *supra* note 1, art 23.

124 *France Monsanto*, *supra* note 13.

125 The 2001 Directive, *supra* note 1, art 23.

126 *Id. supra* note 1, arts 13–39.

additional information' that has been made available since the date of consent, which affects the environmental risk assessment; or, a 'reassessment of existing information on the basis of new or additional scientific knowledge'.<sup>127</sup>

In either case, upon invoking a safeguard clause, a Member State must immediately inform the European Commission and the other Member States of the reasons why the restrictive action was taken. The Commission will then determine, within the timeframe prescribed by the relevant Directive, whether the action to adopt a safeguard clause is deemed justified or not.<sup>128</sup>

*'Derogation from a Harmonization Measure': Article 95(S) of the EC Treaty*  
Article 95(S) of the *EC Treaty*,<sup>129</sup> employed in the *Austrian case*,<sup>130</sup> provides a general mechanism for a Member State to introduce national provisions in response to a harmonisation measure in order to protect the environment. It does not refer specifically to GMOs. Such measures must be based on 'new scientific evidence' in relation to a specific problem arising after the adoption of the harmonisation measure.<sup>131</sup> The Member State notify the Commission, which has six months to review the grounds supporting the decision and can reject the national provision if deemed to be 'a means of arbitrary discrimination', 'a disguised restriction on trade between Member States' and if it constitutes 'an obstacle to the functioning of the internal market'.<sup>132</sup>

*'Emergency Measure': Article 34 of the 2003 Regulation*

The 2003 Regulation concerns genetically modified food and feed on the European market, consisting of: GMOs for food use; food containing or consisting of GMOs; or food produced from or containing ingredients produced from GMOs.<sup>133</sup> Article 34 of that Regulation, employed in *France Monsanto* and *Fidenato case* provides an 'emergency measure' for Member States to suspend or modify an authorisation to market in cases where there is evidence that an authorised product is 'likely to constitute a serious risk to human health, animal health or the environment' or where an urgent need to do so arises from an opinion issued by the EFSA.<sup>134</sup> Procedural requirements are set out in Articles 53 and 54 of the 2003 Regulation,<sup>135</sup> which also include a requirement to notify the Commission which subsequently makes a determination on the merits of the decision by the Member State, and will be discussed more fully in Part III.

127 *Id. supra* note 1.

128 The Commission is required to make a decision 'as soon as possible' pursuant to Article 12 of Novel Foods Regulation, and 'within 60 days', calculated as set out, under Article 23(2) of The 2001 Directive. See Novel Foods Regulation, *supra* note 37.

129 Article 95(S) of the *EC Treaty*.

130 *Austrian case*, *supra* note 12.

131 *EC Treaty*, art 95(S).

132 *Id.* art 6.

133 The 2003 Regulation, *supra* note 40, art 1.

134 *Id.* art 34.

135 *Regulation (EC) No 178/2002 of the European Parliament and of the council of 28 January 2002 on the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety* [2002] OJ L 244/1 arts 53–54 ('*Food Law Regulation*').

Bearing the analysis carried until now in mind, the next Part III will carry out a detailed investigation of the four seminal cases handed down by the CJEU between 2003 and 2017.

### PART III—THE PRECAUTIONARY PRINCIPLE AND GENETICALLY MODIFIED ORGANISMS: ANALYSIS OF FOUR SEMINAL CASES OF THE CJEU (2003–2017)

#### The 2003 Monsanto Italy case: Operationalisation of the Precautionary Principle by means of a Safeguard Clause

##### *Background to the Dispute*

Between December 1997 and October 1998, Monsanto Europe SA, Novartis Seeds AG and Pioneer Overseas Corporation (hereinafter “*Monsanto and others*”), three companies involved in the trade of new GM maize lines, notified the European Commission about their intention to place novel foods or novel food ingredients derived from the maize lines<sup>136</sup> (hereinafter “*novel foods*” or “*novel foodstuffs*”) on the market. This notification was required under Article 5 of Regulation 258/97/EC<sup>137</sup> and was accompanied by supporting opinions from the UK’s Advisory Committee on Novel Foods and Processes, stating that the novel foodstuffs were ‘substantially equivalent to products derived from conventional maize and were safe for use in food’.<sup>138</sup>

The Italian Health Ministry explained its objections and concerns about the introduction of the foodstuffs derived from the GM maize lines into the European market through the use of the simplified procedure.<sup>139</sup> Nevertheless, the Commission did not deem it necessary to adopt any measure against the introduction of the contested products. For this reason, on 4 August 2000, the Italian Government, exercising its right to implement protective safeguard measures under Regulation 258/97,<sup>140</sup> adopted a Decree to suspend trade in and use of the novel foods within Italy.<sup>141</sup>

In order to obtain an opinion about the legitimacy of the Italian measure, the Commission, as provided by Article 11 of Regulation 258/97/EC,<sup>142</sup> consulted the Scientific Committee for Food. Although the information provided by the national authorities did not include any specific scientific reasons to indicate that the GMO-derived food was dangerous for health,<sup>143</sup> the national temporary ban was allowed to stand pending further developments due to the concerns expressed by several Member States about the use of the simplified procedure for novel foodstuffs.<sup>144</sup>

Facing the Italian ban, in November 2000 Monsanto and others brought an action against the Italian Government before the *Tribunale Amministrativo Regionale del Lazio* (hereinafter “*TAR*”), a regional administrative court in Italy, seeking an annulment of the Decree of August 2000 and full compensation for the damage they had suffered

136 Specifically, maize lines Bt-11, MON 810 and MON 809.

137 Novel Foods Regulation, *supra* note 37.

138 *Monsanto Italy*, *supra* note 11, at [19].

139 See Novel Foods Regulation, *supra* note 37.

140 *Novel Foods Regulation*, *supra* note 37, art 12.’

141 *Monsanto Italy*, *supra* note 11, at para [31].

142 *Novel Foods Regulation*, *supra* note 37, art 11.’

143 *Monsanto Italy*, *supra* note 11, at para [35].

144 *Id. supra* note 11, at paras [36], [39].

as a result of the ban.<sup>145</sup> In the circumstances, the TAR stayed the proceedings and submitted questions to the CJEU for a preliminary ruling.<sup>146</sup>

Out of the four preliminary questions that were raised, two key issues were addressed by the court that provide the first set of clues to understanding how the Precautionary Principle is interpreted by Member States and subsequently applied by the CJEU: (i) the concept of substantial equivalence in relation to the appropriateness of the simplified procedure; and (ii) the legitimacy of the national precautionary measure as a result of invoking a 'safeguard clause' under Regulation 258/97.

#### *Legal Reasoning of the Litigants and the Court's Deliberations*

**Substantially Equivalent Foodstuffs and the Simplified Procedure** The first issue concerns the concept of substantial equivalence and the lawfulness of the fast-track approval procedure. Indeed, the assessment of foods as substantially equivalent to conventional items is a pre-condition to determining whether novel foodstuffs should be analysed under a simplified procedure. In this respect, it is important to note the existence of an agreement between the European Commission and Member States within the framework of the Standing Committee for Foodstuffs not to apply the simplified procedure to novel foods derived from GMOs which contain transgenic proteins from January 1998.<sup>147</sup> Since Monsanto's notification had been given prior to reaching that agreement, the CJEU decided to consider the issue regarding the simplified procedure.

While the reasons advanced by the Italian Republic essentially reaffirmed the general concerns of many Member States to use the simplified procedure for new foodstuffs, observations submitted to the European Court by Monsanto and others pointed out that the interpretation of the concept of substantial equivalence is a matter for scientific, rather than legal, determination. They argued further that, since the procedure under Article 5 of Regulation No 258/97 is applicable to foods which are produced from GMOs but do not contain them, as in the present case, only substantial equivalence was at issue.<sup>148</sup>

The Italian Government emphasised that when risk assessment appears necessary, as in this case, Regulation No 258/97 provides for application of the normal procedure (rather than the simplified one), as referred to in Article 3(2); otherwise, the failure of such a necessary assessment would lead to infringement of an aim of Regulation No 258/97 to safeguard public health.<sup>149</sup> The Italian Government referred to Part I, Section 3, point 3.3 of the Annex to Recommendation 97/618/EC<sup>150</sup>, according to which the concept of 'substantial equivalence' is instrumental and relative in nature, clarifying that such a concept and, consequently, the simplified procedure, should 'apply only if the equivalence relates to all the factors identified in Regulation No 258/97

145 *Id. supra* note 11, at para [40].

146 *Id. supra* note 11, at para [48].

147 *Id. supra* note 11, at para [21].

148 Opinion of Advocate General Alber, *supra* note 118, at para [35].

149 *Monsanto Italy, supra* note 11, at para [53].

150 *Commission Recommendation 97/618/EC concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council* [1997] OJ L 253/1 ('*Recommendation on Novel Foods*').



(composition, nutritional value, and so forth).<sup>151</sup> It also added that the presence of transgenic proteins resulting from inserted genes was not disputed. Thus, the simplified procedure could not be applied if it was found that a safety assessment regarding the presence of inserted genes was required.<sup>152</sup>

Throughout the judgment, the CJEU referred to the aims of Regulation No 258/97 in support of its reasoning, namely: to ensure the proper functioning of the internal market when novel foods are involved,<sup>153</sup> and to safeguard public health against the resultant risks.<sup>154</sup> According to the court, this twofold aim supports an interpretation according to which the concept of substantial equivalence does not preclude that novel foods with differences in composition, without proven harmful effects on public health, could be considered substantially equivalent to traditional ones.<sup>155</sup>

The CJEU asserted that the absence of substantial equivalence does not necessarily imply that the foods in question are unsafe, but merely that they should be subject to an assessment about their potential risks.<sup>156</sup>

The court also held that the use of a simplified procedure does not amount to ‘a relaxation of the safety requirements which must be met by novel foods.’<sup>157</sup>

Finally, the court emphasised that if the contested effects were considered dangerous to human health at the time of the initial examination, they would have to be subject to a risk assessment. Consequently, a finding of substantial equivalence would be excluded.<sup>158</sup> Since harmful effects were not identified at the time of the initial examination,<sup>159</sup> the CJEU concluded on the basis of key pleadings claiming that the novel foodstuffs could be considered substantially equivalent to existing foods and, consequently, the use of simplified procedure for their introduction to the market should be allowed.

**Legal Adoption of a Temporary Ban through a ‘Safeguard Clause’ under Article 12 of Regulation No 258/97** In its second and third questions, the Italian National Court had queried: (i) whether, on the basis of the Precautionary Principle, a Member State could adopt a preventive measure suspending the trade of new foodstuffs pursuant to Article 12 of European Regulation No 258/97; and (ii) what effect the valid use of the simplified procedure had on the power of Member States to adopt the above-mentioned measure. As previously indicated, pursuant to Art.12 of Regulation No 258/97, a Member State can either temporarily restrict or suspend trade in and use of a food or food ingredient in its territory if it has been considered harmful for human health or the environment by new scientific knowledge. An analysis of this key issue highlights some contradictory reasoning by the CJEU. The court properly viewed the safeguard clause as a specific expression of the Precautionary Principle; however, the level of evidence it required to implement a precautionary approach was highly

151 *Monsanto Italy*, *supra* note 11, at para [54].

152 *Id. supra* note 11, at para [55].

153 *Novel Foods Regulation*, *supra* note 37, Recital.

154 *Id. supra* note 37, Recital, art 3(1).

155 *Monsanto Italy*, *supra* note 11, at paras [73]–[74].

156 *Id. supra* note 11, at para [75–9].

157 *Id. supra* note 11, at para [80].

158 *Id. supra* note 11, at para [81].

159 *Id. supra* note 11, at para [84].

rigorous, making it difficult to successfully invoke the safeguard clause. Also, while new foodstuffs could be placed on the market through a simplified procedure, a safeguard clause could only be utilised when the Member State first carried out a risk assessment as completely as possible.

According to Monsanto and others, Article 12 Regulation No 258/97<sup>160</sup> allows Member States to act only when new scientific information has been provided, which was not the case for Italy when it had adopted the Decree of August 4, 2000.<sup>161</sup> In response, the Italian Government argued that, under Article 12, a Member State could temporarily suspend trade of novel foods placed on the market under the fast-track approval procedure because they had not undergone a comprehensive safety assessment by virtue of having been placed on the market through a simplified procedure.<sup>162</sup> The national government stressed that, as such, Article 12 should be read in light of the purpose of the Precautionary Principle.

The CJEU first stated that the applicability of Article 12 is not affected by the type of the procedure followed—simplified or normal—nor by the validity of the procedure carried out.<sup>163</sup> After settling this point, the European Court dealt with the central question of whether, in light of the Precautionary Principle, a Member State could adopt a preventive measure suspending the trade of those foods according to Article 12 of European Regulation.<sup>164</sup>

The CJEU argued that, in order to lawfully adopt a temporary restriction or suspension of the trade of novel foodstuffs within a national territory, different substantive conditions had to be satisfied. Firstly, the protective measures adopted under the safeguard clause could not be based on mere suppositions that had not been scientifically validated;<sup>165</sup> secondly, specific evidence of a risk to human health or the environment needs to be provided;<sup>166</sup> thirdly, such measures must be based on a risk assessment that has been carried out as completely as possible in the particular circumstances of each individual case;<sup>167</sup> and finally, the results of the risk assessment carried out must show that the implementation of those measures is necessary in order to ensure that novel foods are not harmful for consumers.<sup>168</sup> A failure to satisfy any one of these conditions will adversely affect, according to the court's reasoning, the aims guaranteed by Regulation No 258/97.

In addition, with regards to the evidentiary threshold, the CJEU stated that Article 12 of Regulation No 258/97 requires a Member State to have 'detailed grounds' when claiming that the use of new foodstuffs damages human health or the environment.<sup>169</sup>

Finally, the CJEU established that a protective measure through the safeguard clause must nevertheless be grounded in the specific evidence provided by the

160 *Recommendation on Novel Foods*, *supra* note 150.

161 Opinion of Advocate General Alber, *supra* note 118, at para [96]; *Monsanto Italy*, *supra* note 11, at para [8].

162 *Monsanto Italy*, *supra* note 11, at para [99].

163 *Id. supra* note 11, at para [104].

164 *Id. supra* note 11, at para [106].

165 *Id. supra* note 11, at para [106].

166 *Id. supra* note 11, at para [113].

167 *Id. supra* note 11, at para [107].

168 *Id. supra* note 11, at para [114].

169 *Id. supra* note 11, at para [108].

competent national authority<sup>170</sup> This is in spite of the acknowledgment that ‘the safeguard clause must be understood as giving specific expression to the Precautionary Principle.’<sup>171</sup>

#### *Court’s Ruling*

In response to the first issue, the CJEU established that use of the simplified procedure to place such foods on the market was permitted<sup>172</sup> because the mere presence in novel foods of residues of transgenic proteins at certain levels does not preclude those foods from being considered substantially equivalent to existing foods.<sup>173</sup> Moreover, the court observed that the circumstances of the case did not highlight the presence of any evidence of a risk of potentially dangerous effects on human health available at the time of the initial assessment.<sup>174</sup>

With regard to the second issue, the CJEU stressed that valid use of the simplified procedure does not affect the power of Member States to adopt safeguard measures according to Article 12 of Regulation No 258/97.<sup>175</sup> Nevertheless, the legal adoption of such measures is provided only when the Member State has first carried out a risk assessment, which must be as complete as possible, and the outcomes of the assessment reveal that, in the light of the Precautionary Principle, the implementation of such a measure is necessary to ensure that a novel food does not present a danger for the consumer.

#### *Analysis of the Case: Can a Member State Operationalise the Precautionary Principle by means of a ‘Safeguard Clause’ without ‘new’ scientific evidence?*

*Monsanto Italy*<sup>176</sup> has provided some early clues regarding the future direction of the CJEU in relation to its treatment of the Precautionary Principle in relation to GMOs based on how the court had substantively handled the national request for operationalise precautionary measures in the context of GMOs. As a result of the court’s approach to scientific evidence regarding risks during that phase, it can be argued that the CJEU limited Member States’ intentions to regulate GMOs precautionary. In doing so, the court favours commercial aims driving a common market over precautionary concerns about human health and the environment. This observation is supported by critical examination of the court’s reasoning in relation to the issue of substantial equivalence in relation to the appropriateness of the simplified procedure to market novel foods or novel food ingredients.

Defining ‘substantial equivalence’ had become a contentious issue throughout the judgment. A finding that a novel food is ‘substantially equivalent’ is important because it makes it possible to utilise a simplified procedure to introduce that novel food into the market. The CJEU held that Regulation No 258/97 supports an interpretation according to which the concept of substantial equivalence: (i) does not preclude that

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170 *Id. supra* note 11, at para [113].

171 *Id. supra* note 11, at para [110].

172 *Id. supra* note 11.

173 *Id. supra* note 11, at para [140.1].

174 *Id. supra* note 11.

175 *Id. supra* note 11, at para [140.2].

176 *Id. supra* note 11.

new foodstuffs with specific features could be considered substantially equivalent to traditional ones;<sup>177</sup> and (ii) should be contextualized through the work of international scientific institutions.

The overarching aims of Regulation 258/97 are: (i) to protect public health against the risks arising from GMOs;<sup>178</sup> and (ii) to ensure the function of the internal market in GM foods.<sup>179</sup> As argued by the CJEU, this supports an interpretation under which:

[T]he concept of substantial equivalence does *not preclude* novel foods which display differences in composition that *have no effect* on public health [or the environment] from being considered substantially equivalent to existing foods.<sup>180</sup>

The CJEU went further to argue that:

[T]he absence of substantial equivalence does *not necessarily imply* that the food in question is unsafe, but simply that it should be subject to an assessment of its potential risks.<sup>181</sup>

It merits noting that simply establishing substantial equivalence does not constitute a full safety assessment, even though it represents a crucial step in the assessment process.<sup>182</sup> Indeed, as provided by Section 3, point 3.3 of Recommendation 97/618/EC, even if a novel food is considered substantially equivalent to an existing one, it should be kept in mind that ‘the establishment of substantial equivalence is not a safety or nutritional assessment in itself.’<sup>183</sup> In that respect, the proposition by the CJEU relating that foods deemed not to be substantially equivalent would still need to be subject to an assessment of potential risks is not controversial.

The above interpretation by the CJEU implies endorsement of a ‘weak’ application of the Precautionary Principle that tolerates differences in composition so long as they have no effect on public health—in the absence of evidence to the contrary—and thereby prioritises the function of the internal market in GMOs. In contrast, a ‘strong’ application of the Precautionary Principle would have held that substantial equivalence *does* preclude novel foods with differences in composition in the *absence of evidence of no effect on public health*. Similarly, the second argued point by the ECJ could be reconceived under a ‘strong’ application of the Precautionary Principle to hold that an absence of substantial equivalence *does* imply that it *might* be unsafe. In other words, the phrasing of the conditions set out by the ECJ in defining ‘substantial equivalence’ reflects a preference for one policy aim over the other, namely in favour of the free circulation of goods.

What is of greater interest relates to the court’s reasoning to endorse the availability of a simplified procedure to place novel foodstuffs on the European market. The CJEU

177 *Id. supra* note 11, at paras [73–4].

178 *Novel Foods Regulation, supra* note 37, Recital para 2, art 3(1).

179 *Id. supra* note 37, Recital para 1.

180 *Monsanto Italy, supra* note 11, at para [74] (emphasis added).

181 *Id.* at para [77] (emphasis added).

182 Opinion of Advocate General Alber, *supra* note 118, at para [44].

183 *Recommendation on Novel Foods, supra* note 150.

justifies the use of a fast-track process by stating that this did not amount to ‘a relaxation of the safety requirements which must be met by novel foods.’<sup>184</sup> Such a statement is inconsistent with the Agreement between the European Commission and Member States to no longer apply the simplified procedure to novel foods derived from GMOs which contain transgenic protein (such as in this case), having effect from January 1998, but which did not apply (in this case) as a result of the timing of the notification and coming into effect of the Agreement.<sup>185</sup>

Further observations could be taken with the court’s reasoning relating to evidentiary factors such as the timing and required threshold of evidence of potential risks. The CJEU argued that evidence about unknown effects that could pose a danger to human health generated *at the time of the initial examination of the product*, would have to be subject to a risk assessment.<sup>186</sup> By limiting the scope of inquiry to scientific knowledge available at the time of the initial assessment, however, does not factor in subsequent development of the scientific knowledge nor account for the slow evolution of novel foods that might occur at a later time. Moreover, the provision of such a limiting temporal parameter implies that novel foods, for which unknown effects may not have been considered harmful to human health at the time of the initial assessment, must not be subjected to a risk assessment later.

The court did not allow Italy to adopt a safeguard measure provided by Article 12 of Regulation No 258/97 in the absence of new scientific evidence about the harmful effects of such foods. Indeed, the CJEU ruled that the national evidence did not reveal a *necessity* to implement safeguard measures in light of the Precautionary Principle, thereby setting the bar for proving risk closer to a standard of ‘certain’ than ‘uncertain’. This approach to domestic evidence emerging from a risk assessment collides with a further key statement issued by the CJEU, according to which ‘the safeguard clause must be understood as giving specific expression to the precautionary principle.’<sup>187</sup> This strict approach to scientific evidence adopted by the CJEU effectively prevented the Member State from triggering the Precautionary Principle to uphold its safeguard measure to ban the GMO maize line.

In a nutshell, the analysis in this section has concluded that the CJEU interpreted the scientific evidence emerging from the risk assessment stage in *Monsanto Italy* by applying a rigid approach that does not provide much scope for a Member State to invoke the Precautionary Principle in support of a ban of GMOs through a safeguard clause under Regulation 258/97. As a consequence, Italy was unable to promote a higher level of protection of human health than the level set by the European Union. This is despite the *Treaty of Lisbon* establishing the protection and improvement of human health as a national area of competence, where EU policy can only intervene to support, coordinate or complement domestic action.

184 *Monsanto Italy*, *supra* note 11, at para [80].

185 *Id. supra* note 11, at para [21].

186 *Id. supra* note 11, at para [81].

187 *Id. supra* note 11, at para [110].

## The 2007 Austrian Case: Operationalisation of the Precautionary Principle by means of a Derogation from a Harmonized Measure

### *Background to the Dispute*

On March 13, 2003, the Republic of Austria provided notice to the European Commission about a draft law of the Land Oberösterreich (Upper Austria) regarding a ban that aimed to prohibit the cultivation of seed and planting material composed of or containing GMOs and the breeding and release of transgenic animals. The aim of the ban was to safeguard the environment and natural biodiversity of the province of Upper Austria from harmful effects of GMO production. The notification was made pursuant to *EC Treaty* Article 95(5), which allows derogation from a harmonisation measure provided that the domestic provisions are based on new scientific evidence relating to the protection of the environment on grounds of a problem specific to that Member State. In support of its ban, the Austrian Republic submitted the 'Müller Report'<sup>188</sup> to the Commission, which sought to demonstrate that a specific problem in the Land Oberösterreich had arisen following the adoption of the 2001 Directive, which made it necessary to derogate from the harmonised measure.<sup>189</sup>

The 'Müller Report' argued that the level of environmental protection afforded by the 2001 Directive was not acceptable due to the problems that had arisen in Austria subsequent to adoption of the Directive.<sup>190</sup> In particular, the Report presented new scientific evidence that indicated a danger for the local environment, emphasising that Upper Austria had a specific farming structure, with small-scale farms and a substantial level of organic farming. The Report also stressed that the problem of coexistence between GM and non-GM crops had not been addressed by the 2001 Directive,<sup>191</sup> and was therefore regarded as unresolved.<sup>192</sup>

Before undertaking its assessment, the Commission requested the EFSA to provide an opinion to determine whether the Müller Report actually provided new scientific evidence. According to the EFSA, the Müller Report provided neither new data capable of invalidating the provisions for environmental risk assessment, nor new scientific evidence in terms of risks to human health or the environment for the purpose of justifying a general ban of the cultivation of genetically modified seeds and propagating material.<sup>193</sup> As a result, the Commission rejected the request of the applicants on two main grounds: (i) first, EFSA's opinion did not corroborate the evidence of 'the Müller Report'; (ii) the 'specific problem' relating to small-sized farms was not deemed to be specific to Upper Austria, but a common feature of several Member States and, for this reason, not deserving of special protection.<sup>194</sup>

188 Werner Müller, *GVO freie Bewirtschaftungsgebiete: Konzeption und Analyse von Szenarien und Umsetzungsschritten Endbericht* (Endbericht, Strobl, 28 April 2002) <[http://www.keine-gentechnik.de/bibliothek/zonen/studien/mueller\\_gvo\\_frei\\_bewirtschaftung\\_020428.pdf](http://www.keine-gentechnik.de/bibliothek/zonen/studien/mueller_gvo_frei_bewirtschaftung_020428.pdf)>.

189 *Austrian case*, *supra* note 12, at para [8].

190 *Id. supra* note 12, at para [42].

191 The 2001 Directive, *supra* note 1.

192 *Id. supra* note 1, para [21].

193 *Opinion of Advocate General Sharpston in Land Oberösterreich and Republic of Austria v Commission of the European Communities*, C-439/05 P and C-454/05 P, EU:C:2007:510, para [24].

194 *Id.* para [44].



The Republic of Austria and the Land Oberösterreich each brought an action before the CFI seeking an annulment of the Commission's decision. After the CFI dismissed the actions in a single judgment, the applicants appealed to the CJEU.

The pleas of the applicants related essentially to: (i) infringement of the right to be heard, since the CFI did not consider that Austria had been unable to respond to an opinion of EFSA; (ii) infringement of the obligation to provide reasons and failing to give adequate consideration to the specific features of Upper Austria; (iii) consequential infringement of the *EC Treaty* Article 95(5); and (iv) breach of the Precautionary Principle by failing to accord it proper weight. Among these issues, only the first and third pleas were expressly addressed by the CJEU. Indeed, the court found the fourth plea relating to a failure to consider the Precautionary Principle to be moot, 'since a request had been submitted to the Commission under *EC Treaty* Article 95(5) and it had already decided that the conditions for application of that provision were not met.'<sup>195</sup>

An analysis of this reasoning of the CJEU in relation to the third plea will shed further light on how the court's interpretation of evidence during the risk assessment phase impacted on the applicability of the Precautionary Principle to support a decision by a Member State to ban GMOs.

#### *Legal Reasoning of the Litigants and the Court's Deliberations*

The applicants submitted that the CFI did not give proper consideration to what they submitted constituted a special feature of farming in Upper Austria, thereby failing both to provide adequate reasons for its decisions as well as to give proper weight to the Precautionary Principle. The crucial issue revolves around the probative value of the scientific evidence contained within the Müller Report. It is important to consider this issue because, once again, a decision by the CJEU to discount evidence put forward by a Member State can inhibit the potential for the Precautionary Principle to be applied successfully—and thereby suggest a failure by the court to provide adequate reasoning for rejecting a ban that would ground its justification in the Precautionary Principle.<sup>196</sup>

The applicants argued that the conditions for the application of Article 95(5) of the *EC Treaty* were satisfied, namely: evidence of *new scientific findings*, a purpose to *protect the environment*, and existence of a *specific problem*. The Republic of Austria relied on the Müller Report, which it presented as new scientific evidence insofar as it had to come to light subsequent to the adoption of the 2001 Directive, which represents the harmonisation measure from which the derogation was sought. They argued that the level of environmental protection afforded by the Directive was not acceptable in relation to the specific nature of farming practices in Upper Austria.

The Austrian Republic stressed that the CFI should have considered the inadequacy of earlier risk assessment and subsequent application of the Precautionary Principle to consider the coexistence of GMOs and natural crops.<sup>197</sup> The appellants also contested the CFI finding of an absence of a specific problem for the purpose of satisfying Article

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195 *Austrian case, supra* note 12, at para [21].

196 Opinion of Advocate General Sharpston, *supra* note 193, para [51].

197 *Austrian case, supra* note 12, at para [47].

95(5) of the *EC Treaty*, which the CFI had determined to be the case as a result of a lack of evidence about the presence of GMOs in the Land Oberösterreich.<sup>198</sup> On a more focused point, the applicants contended that the term ‘specific’ provided by that Article should not be considered synonymous with ‘unique’.<sup>199</sup> They also argued that the Article referred to ‘particular problems’, but not ‘exclusive problems’ of a Member State.<sup>200</sup> This interpretation led the CFI to not examine the other conditions provided by Article 95(5) of the *EC Treaty*, infringing Community Law as a result.<sup>201</sup> The Republic of Austria concluded by adding that the Commission and the CFI, through a restrictive interpretation of the conditions provided by Article 95(5) of the *EC Treaty*, had failed to take into account the Precautionary Principle, which affected the final outcome of the dispute and as a consequence harming its national interests.<sup>202</sup>

In its response, the Commission underscored that *new scientific evidence* and *protection of the environment* could be not considered elements of a *specific problem*, ‘but that all three are cumulative conditions for the application of art. 95(5) EC’;<sup>203</sup> consequently, if even one condition has not been satisfied, then the request has to be rejected.<sup>204</sup> With regard to the Precautionary Principle, the Commission merely corroborated the explanation provided by the CFI in rejecting the plea concerning its infringement.<sup>205</sup> Finally, in response to the alleged infringement of Community Law as a result of misinterpreting of the term ‘specific’ within Article 95(5) of the *EC Treaty*, the European Commission concluded that the appellants had failed to prove, as required by Article 95(5) of the *EC Treaty*, the existence of a specific problem by having ‘confined themselves to basing their argument on the small size of farms and on the importance of organic production.’<sup>206</sup>

According to the CJEU, Article 95(5) of the *EC Treaty* requires that the introduction of a domestic provision derogating from a harmonisation measure—in this case, provisions of the 2001 Directive—must be supported by new scientific evidence. It should be also considered imperative that the Member State address a specific problem which arose after the adoption of the harmonised measure.<sup>207</sup>

The CJEU thus upheld the reasoning of the CFI and the findings of Commission, reinforcing the view that the Republic of Austria had not adduced further scientific evidence.<sup>208</sup> The court held that, as a result of this the failure by the Member State to give evidence as a critical condition required by Article 95(5), the CFI and Commission did not err in dismissing the actions of appellants without seeking to ascertain whether other conditions were been satisfied due to the cumulative nature

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198 *Id. supra* note 12, at para [48].

199 *Id. supra* note 12, at para [54].

200 *Id. supra* note 12.

201 *Id. supra* note 12.

202 *Id. supra* note 12, at para [49].

203 *Id. supra* note 12, at para I-7162 [56].

204 *Id.*

205 *Id. supra* note 12, at para [52].

206 *Id. supra* note 12.

207 *Id. supra* note 12, at para [57].

208 *Id. supra* note 12, at para [66].

of those conditions.<sup>209</sup> Consequently, the CFI had not infringed Article 95(5) of the *EC Treaty*.<sup>210</sup>

#### *Court's Ruling*

The CJEU held that the CFI had not erred by confining itself to analyse only the condition concerning the existence of a problem specific to the Member State. It declared that the arguments of the appellants relating to its right to be heard and breach of Article 95(5) of the *EC Treaty* were ill-founded and based on irrelevant arguments. The case was therefore dismissed.<sup>211</sup>

*Analysis of the Case: Can a Member State Operationalise the Precautionary Principle by means of a 'Derogation from a Harmonisation Measure' without 'new' scientific evidence?* As with Republic of Italy, Austria tried unsuccessfully to uphold a ban of GMOs in its jurisdiction by relying on a precautionary approach. Instead of acting through a 'safeguard clause', Austria attempted to trigger the Precautionary Principle by invoking Article 95(5) of the *EC Treaty* to uphold its 'derogation of a harmonisation measure' that was contained within the 2001 Directive.<sup>212</sup> Despite the different approaches, this case raises similar concerns about the court's interpretation of evidence emerging from the risk assessment phase, which ultimately resulted in pre-empting full consideration of the Precautionary Principle during the subsequent risk management phase.

As with *Monsanto Italy*, the *time-factor* for producing evidence in relation to potential risks associated with GMOs is crucial in both a procedural and substantive way. The procedural limitation serves as a gatekeeper for evidence to be duly considered as part of the normative parameters of the Precautionary Principle. Under Article 95(5) of the *EC Treaty*, 'new scientific evidence' must be provided in relation to a problem arising after the adoption of the harmonisation measure.<sup>213</sup> This requirement is problematic because it is not always possible to establish the exact moment at which an environmental issue arises, which highlights the disconnect between the nature of scientific uncertainty and procedural requirement of the court.

The consequence of excluding evidence at the risk assessment stage can undermine the integrity of the risk management stage in which the Precautionary Principle is applied without reference to all available evidence. In the *Austrian case*, two conflicting reports were put before the court—the 'Müller Report' and the opinion of EFSA—regarding the effects of GMOs.<sup>214</sup> By dismissing the 'Müller Report', the CJEU appears to dismiss national concerns based on a narrow interpretation of the conditions set out under Article 95(5) of the *EC Treaty*. It relied exclusively on the EFSA opinion. This might raise concern about limitations on the discretionary power to Member States to implement a precautionary approach.<sup>215</sup>

209 *Id. supra* note 12, at paras [68]–[70].

210 *Id. supra* note 12, at para [72].

211 *Id. supra* note 12, at paras [71]–[74].

212 The 2001 Directive, *supra* note 1.

213 *EC Treaty*, art 95(5).

214 The *Austrian case*, *supra* note 12.

215 Floor M Fleurke, *What Use for Article 95 (5) EC ? An Analysis of Land Oberosterreich and Republic of Austria v Commission*, 95 J. ENVIRON. LAW 267–278, 273 (2008).

As with Italy, Austria was denied the possibility of adhering to a higher level of protection of human health than the level of chosen by the European Court. This outcome can of course be rationalised as the result of balancing competing policy interests during the risk management phase. However, it merits recognising that the outcome was not based on a genuine exercise of balancing interests, but as the inevitable conclusion resulting from the court's exclusion of evidence (offered in the 'Müller Report') that would otherwise have informed the risk management stage where policy interests are to be considered. In this respect, the question arises as to the appropriateness of a narrow approach to evidence during the risk assessment phase, especially in an indefinite field such as the genetic engineering in which the degree and extent of impact on human health and the environment cannot be readily quantified.

As underlined by Advocate General Sharpston, the CFI and CJEU failed in their duty to provide adequate reasoning by virtue of not having examined all of the evidence in light of the Precautionary Principle.<sup>216</sup> He also explained that the notion of 'new scientific evidence' is a highly controversial point, considering the nuances of translation of Article 95(5) of the *EC Treaty* in different languages.<sup>217</sup>

This would suggest that what the CJEU considers 'new scientific evidence' is open to interpretation. As the CJEU chose to apply a narrow approach in the *Austrian case*,<sup>218</sup> it effectively prioritised one policy aim (to promote a common market) over the other at stake (to provide a higher standard of health or environmental protection than the EU).

Although it was not reported by the CJEU in its judgment, the Commission had submitted two proposals to the Environment Council in relation to the maize line in question.<sup>219</sup> In its first declaration, the Council argued that 'there is still a degree of uncertainty in relation to the national safeguard measures on the market of [the] genetically modified maize variet [y] [ . . . ] MON810'.<sup>220</sup> For this reason, the European Commission was invited to gather further evidence on the contested GMO and to further assess the justifiability of the Austrian precautionary measure.<sup>221</sup>

Thus, through its first declaration, the Council justified dismissal of the European Commission's proposal, stressing the high level of uncertainty surrounding GMOs, and for this reason calling for further evidence before denying the domestic request to apply a precautionary approach.

In the face of Council's refusal, the European Commission again consulted the EFSA, requesting the consideration of any further scientific information that had arisen subsequent to the previous scientific opinion concerning the safety of this GMO.<sup>222</sup> Once it received a new opinion from EFSA,<sup>223</sup> the European Commission

216 Opinion of Advocate General Sharpston, *supra* note 193, para [51].

217 *Id. supra* note 193, para [124].

218 *Austrian case*, *supra* note 12.

219 *Proposal For a Council Decision Concerning The Provisional Prohibition Of The Use And Sale In Austria Of Genetically Modified Maize (Zea Mays L. Line MON810) Pursuant To Directive 2001/18/EC Of The European Parliament And Of The Council*, COM(2007) 586, (2007) 6 [9]–[10] <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52007PC0586>.

220 *Id.* 6–7(13).

221 *Id. supra* note 219.

222 *Id. supra* note 219, 7(14).

223 The EFSA had concluded its first opinion on 8 July 2004.

submitted a new proposal to the Council to require repeal of the Austrian safeguard measure.<sup>224</sup>

In December 2006, the Environment Council, re-stated its opposition to the European Commission's proposal<sup>225</sup> by observing that 'the different agricultural structures and regional ecological characteristics in the European Union need to be taken into account in a more systematic manner in the environmental risk assessment.'<sup>226</sup> This second denial by the Council highlights the importance of carrying out a systematic risk assessment to address national concerns, and underscores the problem posed by a high level of uncertainty in the assessment of GMOs and corresponding need for greater rigour in the risk assessment stage.<sup>227</sup>

As in the *Monsanto Italy*,<sup>228</sup> Austria lost its bid to uphold a ban to restrict GMOs within its national territory, with the court ascribing greater value to a position based on an incomplete scientific knowledge than the express desire of a Member State to implement a precautionary approach. Together, these first two cases suggest an emerging trend whereby the application of the Precautionary Principle is beholden to the approach taken by the CJEU. The analysis of the third and fourth cases will provide further support for this observation.

**The 2011 France Monsanto and the 2017 Fidenato case: Operationalisation  
of the Precautionary Principle by means of an 'Emergency Measure'  
(along with a Safeguard Clause)**

*Background to the Disputes*

The *France Monsanto* case arose when in 1995, the multinational company Monsanto by relying on Directive 90/220/EEC—which was subsequently replaced by the 2001 Directive—requested permission to import and cultivate MON810 maize in France, submitting the application to France who forwarded it to the Commission and informed the other Member States in accordance with the notification procedure set out in the Directive.<sup>229</sup> Facing the objection of Member States, the European Commission consulted the Scientific Committee on Plants (SCP). The SCP did not find any evidence of possible adverse effects on human health or environment deriving from the novel food. Consequently, on the basis of Directive 90/220, the Commission authorised the introduction of MON 810 maize on the European market of MON 810 maize in 1998. Four months after the European authorisation, the French Minister for Agriculture and Fisheries gave its written consent to place the product on the market.<sup>230</sup>

In 2004, Monsanto duly notified the Commission of MON 810 maize as an 'existing product' under the 2003 Regulation.<sup>231</sup> Before the expiry of its permission to trade, Monsanto applied for renewal of its authorisation to place the MON 810 maize on

224 Proposal for a Council Decision, *supra* note 219, 7(16).

225 *Id.* *supra* note 219, 7(17).

226 *Id.* *supra* note 219, 7(18).

227 *Id.* *supra* note 219, 7(18).

228 *Monsanto Italy*, *supra* note 11.

229 The product was (and it is still) subject to the provisions of the 2003 Regulation, *supra* note 40.

230 Patricia B. Robbins, *GMO Reignited in Science but Not in Law: A Flawed Framework Fuels France's Stalemate*, 69 FOOD DRUG LAW J. 429, 431 (2014).

231 The 2003 Regulation, *supra* note 40, art 20(1a).

the market under the same of the 2003 Regulation,<sup>232</sup> rather than through the 2001 Directive<sup>233</sup> which had replaced Directive 90/220/EEC under which the product had been initially approved in 1998.

While Monsanto's application for renewal was pending at the EU level, the French Minister of Agriculture and Fisheries first suspended the transfer and use of such modified seeds in its national territory, and then prohibited the planting of maize seed varieties derived from maize MON 810 until a decision on the renewal of the authorisation had been taken.<sup>234</sup> The French Minister notified the Commission of its action, classifying it first as an 'emergency measure' in accordance with Article 34 of the 2003 Regulation<sup>235</sup> and Articles 53 and 54 of Regulation No 178/2002,<sup>236</sup> and then also as a 'safeguard clause' pursuant to Article 23 the 2001 Directive.<sup>237</sup>

In the face of this national ban, Monsanto and other companies (hereinafter 'Monsanto and others') brought an action for an annulment of the French order before the Conseil d'État,<sup>238</sup> which decided to stay the proceeding for annulment of the French order and refer the matter to the CJEU for a preliminary ruling.<sup>239</sup>

The CJEU discussed 'whether, if the only emergency measures that can be used are those referred to in Article 34 of the regulation (. . .) a Member State may none the less adopt unilateral measures as the French Republic did in the present case'.<sup>240</sup> The court was also called to establish what conditions, in particular as regards possible risks and taking into account the Precautionary Principle, justify the adoption of measures taken under Article 23 of the 2001 Directive and Article 34 of the 2003 Regulation.<sup>241</sup>

As will be explained in the analysis below, this judgement 'could have significant legal-political and practical consequences for EU multi-level governance of GMOs'.<sup>242</sup>

A few years after the *France Monsanto's* ruling, the CJEU addressed the *Fidenato case*, which arose with the Italian Government's request to the European Commission for adopting a ban prohibiting the cultivation of GM Maize 810 on the Italian territory by means of the emergency measures under Article 34 of the 2003 Regulation. Facing this request, the European Commission asked for the EFSA's opinion on the scientific evidence presented by Italy to support its request. As the EFSA found the lack of new scientific evidence supporting the harmfulness of the contested maize, the European Commission rejected the national request. Nonetheless, the Italian

232 *Id. supra* note 40, art. 20(4).

233 The 2001 Directive, *supra* note 1.

234 In the same year, the Commission on Genetic Modification (COGEM)—an independent scientific advisory committee—supported the safety of MON810, recommending Europe to renew the expiring authorization required by Monsanto.

235 The 2003 Regulation, *supra* note 40, art 34.

236 *Food Law Regulation*, *supra* note 135, arts 53–4.

237 The 2001 Directive, *supra* note 1, art 23.

238 The Conseil d'État is the highest French administrative authority.

239 *France Monsanto*, *supra* note 13.

240 *Id. supra* note 13, 14.

241 *France Monsanto*, *supra* note 13, at para [38].

242 Maria Weimer, *The Right to Adopt Post-Market Restrictions of Genetically Modified Crops in the EU—A Shift from De-Centralised Multi-Level to Centralised Governance in the Case of GM Foods*, 3 EUR. J. RISK REGUL. 445, 449 (2012).



Government issued a national Decree prohibiting the cultivation of GM Maize 810 on the Italian territory. In light of this Decree, Mr Giorgio Fidenato and Others (the Applicants) were prosecuted for having cultivated GM Maize 810 in Italy. Considering the Decree as unlawful, the Applicants lodged an opposition against the panel order.

Before taking any decision, the Italian Tribunal asked the CJEU the preliminary question of whether the emergency measures under article 34 of the 2003 Regulation can be applied in light of the Precautionary Principle, without satisfying the conditions in this Article.<sup>243</sup>

### *Legal Reasoning of the Litigants and the Court's Deliberations*

#### *Legal Adoption of Unilateral Measures by Member States*

In *France Monsanto*, the national court aimed to examine whether a Member State could adopt unilateral measures other than as referred to in Article 34 of the 2003 Regulation.<sup>244</sup>

Monsanto and others, supported by the Commission, based their arguments on a systematic reading of Article 34 of the 2003 Regulation<sup>245</sup> that, in order to adopt emergency measures, refers to the procedure set out in Articles 53 and 54 of Regulation No 178/2002.<sup>246</sup> They claimed that a Member State could not adopt unilateral emergency measures without having first informed the Commission and requested it to act under Article 53 of Regulation No 178/2002.<sup>247</sup> A national government could take unilateral measures only in a case where the Commission fails to act, as set out in the Regulation.<sup>248</sup>

In contrast, the French Government suggested a different interpretation of Article 53. It was argued that, according to this provision, the Commission has to adopt appropriate measures where the problem 'cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned.'<sup>249</sup> In other words, as was also observed by the Advocate General Mengozzi, according to a literal reading of the Article, Member States should have a primary role to adopt emergency measures.<sup>250</sup>

The CJEU established that if a Member State intends to adopt emergency measures pursuant to Article 34 of the 2003 Regulation, it has to comply with the substantive conditions provided by that Article, as well as the procedural conditions laid down by Article 54 Regulation No 178/2002.<sup>251</sup> According to the procedure set out by the latter Article, a Member State, must first notify the Commission of its intention to adopt emergency measures, and only then, if the Commission does not act according

243 See Part II, Section D.3

244 The 2003 Regulation, *supra* note 40, art 34.

245 *Id.* *supra* note 40, art 34.

246 *Food Law Regulation*, *supra* note 135, arts 53–4.

247 *France Monsanto*, *supra* note 13, at paras [30–2].

248 *Opinion of Advocate General Mengozzi*, (Joined Cases C-58/10 to C-68/10) [2011] ECR 00000, at para 26, at para 47.

249 *Food Law Regulation*, *supra* note 135, art 53(1).

250 *Opinion of Advocate General Mengozzi*, *supra* note 248, at para 49.

251 *Id.* *supra* note 248, at para [69].

to Article 53, can the Member State adopt an interim protective (after which it must immediately inform the Commission and other Member States).<sup>252</sup>

On this point, the CJEU made explicit reference to its decision in *Monsanto Italy*,<sup>253</sup> and concluded that a Member State is authorized to adopt emergency measures pursuant to Article 34 of the 2003 Regulation, but only if the emergency measures was adopted in accordance with the procedural conditions set out in Article 54 Regulation No 178/2002/EC, compliance with which (as in this case) should be ascertained by the national court of reference.<sup>254</sup>

**Conditions for the Adoption of Emergency Measures in Light of the Precautionary Principle** A further issue relates to the nature of requirements imposed by Article 23 of the 2001 Directive<sup>255</sup> and Article 34 of the 2003 Regulation.<sup>256</sup> This issue was not argued by the parties, but was rather a point of deliberation by the court. Specifically, the French Court considered the correct reading and legal application of the protective measures by Member States in the light of the Precautionary Principle.

By interpreting the wording of Article 34 of the 2003 Regulation concisely, the CJEU stated that the expressions ‘likely’ and ‘serious risk’ in the text of the Article have to be understood as referring to a significant risk that clearly jeopardises human health, animal health or the environment.<sup>257</sup> Moreover, it added that the presence of a risk must be established by reference to new evidence based on reliable scientific data.<sup>258</sup> With regard to the degree of risk, the court, explicitly referred to the *Monsanto Italy*,<sup>259</sup> and declared that measures pursuant to Article 34 of the 2003 Regulation must not be based on a hypothetical approach to the risk, but ‘may be adopted only if they are based on a risk assessment which is as complete as possible in the particular circumstances of an individual case, which indicate that those measures are necessary.’<sup>260</sup>

The CJEU also emphasized that when an emergency measure is adopted by a Member State, the national courts are competent to assess the legality of these measures in light of Article 34 of the 2003 Regulation and Article 54 Regulation No 178/2002.<sup>261</sup> It is the duty of the CJEU to ensure the uniformity of European Union law, but only after the matter had been addressed by a national court.<sup>262</sup> However, when the Standing Committee on the Food Chain and Animal Health is consulted by the Commission as part of the court’s assessment in a case, the final decision adopted at European Union level (along with the related factual and legal assessments) must be considered ‘binding on all bodies of the Member State which is the addressee of such a decision.’<sup>263</sup>

252 *Id. supra* note 248, at para [70].

253 *Monsanto Italy, supra* note 11, at para [110].

254 *Id. supra* note 11, at para [74].

255 The 2001 Directive, *supra* note 1, art 23.

256 The 2003 Regulation, *supra* note 40, art 34.

257 *France Monsanto, supra* note 13, at para [75].

258 *Id. supra* note 13, at para [76].

259 *Monsanto Italy, supra* note 11, at paras [106–7].

260 *France Monsanto, supra* note 13, at para [77].

261 *Id. supra* note 13, at para [79].

262 *Id. supra* note 13.

263 *Id. supra* note 13, at para [80].

The CJEU concluded by reiterating that, in addition to *urgency*, Article 34 of the 2003 Regulation requires Member States to establish the existence of a situation that is likely to constitute a *clear and serious risk* to human health, animal health or the environment.<sup>264</sup>

It should be noted that no reference was made by the CJEU to the Precautionary Principle, even if explicitly required by the national court, nor did it provide any explanation of the different formulation of conditions laid down by Article 23 the 2001 Directive and Article 34 of the 2003 Regulation.

The brief and concise preliminary judgment issued by the court in *Fidenato case* does not need to be set out in a dedicated section as it is closely aligned with the judicial reasoning in *France Monsanto*.<sup>265</sup> Indeed, by referring back to its 2011 ruling, the CJEU remarked that the adoption of emergency measures under Article 34 requires (i) *evident and serious risk* which is established on the basis of new evidence based on reliable scientific data,<sup>266</sup> and (ii) ‘*a risk assessment which is as complete as possible*’ in circumstances indicating ‘that those measures are *necessary*’.<sup>267</sup>

#### *Court's Rulings*

In *France Monsanto*, the CJEU held that Member States could adopt emergency measures under Article 34 of the 2003 Regulation only in accordance with the procedural conditions set out in Article 54 of Regulation 178/2002. Member States must also demonstrate urgency as well as the existence of clear and serious risk to human health, animal health or the environment. In so doing, Member States must rely on ‘*a risk assessment which is as complete as possible* in the particular circumstances of an individual case, which indicate that those measures are necessary’.<sup>268</sup>

In *Fidenato case*, the CJEU delivered in 2017 its preliminary ruling in which it was established that emergency measures under Article 34 of the 2003 Regulation cannot be adopted solely in light of the Precautionary Principle.

#### *Cases Analysis: Can a Member State Operationalise the Precautionary Principle by means of an ‘Emergency Measure’ without ‘new’ scientific evidence?*

*France Monsanto*<sup>269</sup> revolves primarily around procedural issues insofar as it relates to actions taken in relation to a GM product authorized by a Directive that is no longer in force (Directive 90/220/EEC),<sup>270</sup> and then notified to the Commission as an ‘existing product’ under a newer Regulation.<sup>271</sup> The identification of MON 810 maize as ‘existing’ allowed the company to renew its expiring authorization to place such product on the European market without undergoing a new risk assessment under

264 *Id. supra* note 13, at para [81].

265 For a thorough analysis of *Fidenato case*, see Alessandra Guida, *The 2017 Fidenato case and the 2015 Directive: The curious case of GMOs in Europe*, REV. EUR. COMP. INT. ENVIRON. LAW 1–10 (2020).

266 *Fidenato case*, *supra* note 14, at p 6. (emphasis added).

267 *Id. supra* note 14.

268 *France Monsanto*, *supra* note 13, at para [77].

269 *Id. supra* note 13.

270 The 2001 Directive, *supra* note 1.

271 Indeed, a novel food can be notified as ‘existing product’ according to the conditions set out in the 2003 Regulation, *supra* note 40, art 20.

the more stringent provisions of the 2001 Directive<sup>272</sup> (which had replaced Directive 90/220/EEC). This outcome reflects a less stringent approach to evidence because it allowed Monsanto to maintain its product on the market on the basis of a less demanding (and less recent) risk assessment than would have been required under the new Directive. This is not necessarily inconsistent with the general requirement for the re-assessment of GMOs under the European framework to be undertaken only when new scientific knowledge suggests potential harmful effects. Indeed, under the Recital of the 2001 Directive, GMOs ‘which have conventionally been used in a number of applications and have a long safety record’ are to be excluded from reassessment.<sup>273</sup> By placing the onus on the French Government to provide new scientific evidence to support its ban, the Commission effectively treated Monsanto’s product as a long-standing product that should be excluded from re-assessment.<sup>274</sup>

This outcome, however, stands in contrast to the stricter approach imposed by the court on Member States to invoke an emergency measure under Article 34 of the 2003 Regulation only after providing a risk assessment that is as ‘complete as possible’ and only when ‘necessary’.

A further similarity in approach to evidence emerges when this case is considered against *Monsanto Italy*, in which, the CJEU permitted access to a simplified procedure to market novel foods derived from GMOs which contained transgenic proteins. This is in spite of the agreement between Member States and the Commission that the simplified procedure would no longer be available (noting that this agreement was not in place at the time of notification of the novel product). The court justified this decision on the basis that use of a fast-track procedure did not amount to a relaxation of the safety requirements that must be met by novel foods. In *France Monsanto*, the court appears to have once again facilitated an expedited process by not requiring a new risk assessment in line with revised criteria under the new Directive.

In *France Monsanto*, the court explicitly acknowledges Article 34 of the 2003 Regulation as a valid mechanism for Member States to suspend or prohibit the GMOs use or sale. However, as with the preceding cases discussed in this Part, the practicality of the availability of this mechanism does not appear to support the spirit of a precautionary approach under the emergency measure provided by Article 34, nor through the claimed intention to interpret the national provision in the light of the Precautionary Principle.<sup>275</sup> According to the interpretation of the CJEU, Article 34 of the 2003 Regulation allows the legal adoption of the related emergency measures by Member States only when they can prove the presence of a situation characterized by *urgency* in addition to the existence of *clear and serious risk* to human health, animal health or the environment.<sup>276</sup> Moreover, a measure must rely on *new evidence based on reliable scientific data*.<sup>277</sup>

As a final point of reflection on this case, it merits recalling that the CJEU did not provide detailed reasoning in the *Austrian case* in relation to the issue of new

272 The 2001 Directive, *supra* note 1.

273 *Id. supra* note 1.

274 Robbins, *supra* note 230, at 436.

275 *France Monsanto*, *supra* note 13, at para [71].

276 Opinion of Advocate General Mengozzi, *supra* note 248, at paras 66–7.

277 *France Monsanto*, *supra* note 13, at para [76].

scientific evidence.<sup>278</sup> Similarly, in *France Monsanto*, the court did not explain how the reading of the conditions under which protective measures set out by Article 23 of the 2001 Directive and Article 34 of the 2003 Regulation could be invoked in relation to the Precautionary Principle, nor did it address the third question put forward by the national court.<sup>279</sup> This lack of elaboration of the questions that would serve to provide guidance on protective measures disregards interests of Member States to implement a precautionary approach in the field of GMOs.

The manner in which the CJEU interpreted scientific evidence emerging from the risk assessment stage was met by strong objections by the French Government. For this reason, notwithstanding the deliberation of the CJEU in September 2011 and the following act in November 2011 by the Conseil d'Etat which declared the ban of 2008 on the cultivation of MON 810 to be illegal, the French Government on February 20, 2012 submitted to the EC an 'emergency measures document',<sup>280</sup> extending the prohibition of MON 810 cultivation.<sup>281</sup> This novel document was supported by new documentation as evidence of the necessity to adopt emergency measures on French territory to avoid harmful effects of genetically modified product contested in the European judgment. The French document cited 'environmental risks'<sup>282</sup> because it contains new and important scientific data concerning risks to the environment not previously examined by EFSA's GMO Panel.<sup>283</sup> Even so, the GMO Panel again found no new scientific evidence to support an emergency measure regarding MON 810.<sup>284</sup> Consequently, in August 2013, the Conseil d'Etat again declared the French ban to be illegal.<sup>285</sup> Nevertheless, the French President François Hollande confirmed an extension of the moratorium on the cultivation of Monsanto's GM maize MON 810.<sup>286</sup>

The strict judicial interpretation of the legal mechanisms adopted by Member States to implement precautionary measures emerges again in the *Fidenato case* judgment, which seems to be a déjà vu of *France Monsanto* and, to same extent, *Austrian case*. Similarly to the previous rulings, the strict interpretation of the conditions set out in Article 34 does not seem to leave room for a precautionary reading of the related emergency measures.

278 Advocate General Mengozzi offered an alternative reading of Article 34 which would be more favourable to a precautionary approach. See Opinion of Advocate General Mengozzi, *supra* note 248, at para 68.

279 A detailed comparison between the conditions laid down by Article 23 the 2001 Directive and Article 34 of the 2003 Regulation can be found in Opinion of Advocate General Mengozzi, *supra* note 248, at paras 57–71.

280 Marcel Kuntz, John Davison & Agnès E Ricroch, *Supplementary Information 1— to The French Government Ban of Bt MON 810 Maize Undermines Science-Based Risk Assessment—A Note from the French authorities to the European Commission*, 31 NAT. BIOTECHNOL. 498 (2013).

281 Marcel Kuntz, John Davison & Agnès E Ricroch, *What the French Ban of Bt MON810 Maize Means for Science-Based Risk Assessment*, 31 NAT. BIOTECHNOL. 498, 498 (2013).

282 Robbins, *supra* note 230 at 432.

283 See Kuntz, Davison, and Ricroch, *supra* note 281 at 498. See also Enrica Blasi, *I nuovi margini del potere decisionale degli stati europei in materia di organismi geneticamente modificati*, 1 RIV. QUADRIMESTRALE DI DIRIT. DELL'AMBIENTE 150, 157 (2015).

284 Robbins, *supra* note 230 at 433.

285 *Id.* at 433.

286 French President Confirms Ban on Monsanto's GM Maize MON810, Sustainable Pulse (August 2, 2013) 1 < <http://sustainablepulse.com/2013/08/02/french-president-confirms-moratorium-on-monsantos-gm-maize-mon810/#.V1-EQPmqpBc>.

The CJEU highlights two key differences between the Precautionary Principle, as defined by Article 7 of the 2002 Regulation, and the emergency measures under Article 34 of the 2003 Regulation.

Firstly, the CJEU points out that whereas Article 34 requires ‘evidence’ that authorized products are likely to constitute a serious risk, Article 7, which gives expression to the Precautionary Principle, ‘is *subject to the condition* that, following an assessment of available information, the possibility of harmful effects on health is identified but that scientific uncertainty persists.’<sup>287</sup> This statement ignores the fact that precautionary actions do not depend on the presence of uncertainty but, rather, on a threat of harm.

Given that, a number of questions arise: Should the Precautionary Principle lower the level of evidence required by the CJEU to interpret the emergency measures under Article 34 of the 2003 Regulation? If so, why does the court argue that the principle cannot be used to *relax* the conditions laid down in this Article? Put differently, if the principle should not lower the level of evidence required to interpret emergency measures, how could precaution be implemented in the context of Article 34? The brief ruling does not provide an answer to these questions. This is not the first time, however, that the CJEU does not clarify what level of scientific evidence is required to trigger precautionary measures. In the *Austrian* case, for instance, the Advocate General Sharpston stresses that the CFI and CJEU failed in their duty to provide adequate reasoning on the principle by virtue of not having examined the evidence in light of the Precautionary Principle.<sup>288</sup>

Secondly, the court in *Fidenato* case remarks the difference in *procedural operation* between Articles 7 and 34<sup>289</sup> and its reasoning suggests that the Precautionary Principle is not needed in the *Fidenato* case because the contested product has already been scientifically assessed. ‘Because a full scientific review has already taken place,’ the Advocate General Bobek observes, ‘in order to adopt emergency measures under Article 34, a *higher level of evidence* must be established (. . .). It is also quite clear that Article 34 should not be used *as a way to circumvent the authorisation or disregard the scientific assessment* that was carried out at that stage.’<sup>290</sup>

Bobek uses this justification to argue against the application of precaution in the *Fidenato* case. However, there are two points that can be made with respect to this reasoning—given by the Advocate General and recalled by the CJEU. First, the ongoing scientific debate on the adverse effects of GMOs on human health and the environment arguably precludes the possibility that ‘a *full* scientific assessment of the contested products has already taken place.’<sup>291</sup> After all, this case represents an example of the current, polarised scientific debate: Whereas the Italian Government argued that the GMO cultivation ban was based on new scientific studies proving the harmfulness of GM Maize 810, the EFSA concluded that there was a lack of new scientific evidence showing the harmfulness of this maize. Second, even if the contested product has already been scientifically assessed, the Precautionary Principle can still be applied since it does not depend on scientific uncertainty but rather it can be triggered in spite of

287 *Fidenato* case, *supra* note 14, at p 6 (emphasis added).

288 Opinion of Advocate General Sharpston, *supra* note 193, para 51.

289 Opinion of Advocate General Bobek in *Giorgio Fidenato and Others*, C-111/16, EU:C:2017:676, at paras 74–76.

290 Opinion of Advocate General Bobek, *supra* note 289, at para 77 (emphasis added).

291 *Id. supra* note 289, at para 76.



it. As such, it might be argued that the CJEU's rejection of the Italian request is based on a misperception of the relationship between the Precautionary Principle and scientific knowledge.

Therefore, also in the 2017 judgment, the lack of 'new' scientific evidence represents a key reason preventing the CJEU from allowing the operationalisation of precautionary measures.

### CONCLUSIONS

The analysis of the the jurisprudential path of the CJEU on the Precautionary Principle has highlighted that since 1983 to 2018, a copious number of European decisions have given voice to national requests for taking precautionary actions in different contexts. This manuscript shows however a standstill in the jurisprudence of the CJEU on the Precautionary Principle in the specific context of GMOs. This invites to draw two main findings.

The first key finding relates to the significance of 'new' scientific evidence as a necessary pre-condition for a Member State to validly take a precautionary measure to ban a GMO within its territory. This was clearly established in *Monsanto Italy* where the court ruled that Italy had not provided any new evidence to support its position that the ban was necessary. This requirement was further endorsed in the *Austrian case*, which established not only that the lawfulness of a national measure is closely linked to the scientific evidence put forward, but that this must be 'new scientific evidence' as interpreted by the court. The request for 'new' evidence was also sustained in *France Monsanto*, which held that the 'emergency measure' under Article 34 of the 2003 Regulation must rely on 'new evidence based on reliable scientific data' and in *Fidenato case* by referring back to *France Monsanto*.

The second key finding is in the form of an observation that the CJEU's approach to evidence in the risk assessment stage effectively pre-empts expression of the Precautionary Principle to provide a high level of protection for health and the environment as intended by the EU policy framework.

The above key findings raise several implications for understanding the Precautionary Principle and regulation of GMOs in Europe. Whether or not the court had erred in its decision-making is open to debate, given that the outcomes of each case ultimately relied on key issues that were open to interpretation. Had the court interpreted the evidentiary matters referred to in the first two findings differently, it would likely have led to different outcomes. The fact that courts have to interpret complex scientific evidence and could come to two opposite verdicts based on the same evidence is not ideal. Accordingly, the time seems to be mature for a clearer legislation on the regulation of GMOs in Europe. The current global pandemic is showing us the importance of taking effective precautionary measures in spite of remaining scientific uncertainties. In drafting a new legislation on GMOs, the legislator should bear this lesson in mind. After all, the precautionary principle remains a key tenet of the European legislative framework and it is often recalled, although not thoroughly analysed, by European Courts. For instance, also the recent 2018 judgment of the CJEU on the regulatory status of genome-edited crops offers interesting deliberations on the Precautionary Principle.<sup>292</sup> Unlike the cases examined in this article, the 2018 case required the

292 *Confédération paysanne and Others v Premier ministre and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt*, C-528/16, EU:C:2018:583 ('*Confédération paysanne and Others*').

CJEU to address the question of whether crop plants in which the genetic material was modified with targeted mutagenesis techniques are subject to the European restrictive GMO regulations.<sup>293</sup> In addressing this question, the CJEU acknowledged that the 2001 Directive ‘seeks to implement’ the Precautionary Principle and applies to targeted mutagenesis.<sup>294</sup> This decision might invite to argue that the European Court wanted to ensure effective operationalization of the precautionary principle in the context at hand. Nevertheless, as the court was quite tight-lipped on the questions concerning the applicability of the Precautionary Principle, this argumentation is purely speculative. This strengthens the analysis of the four cases in this article, which has shown that the CJEU does not seem inclined to offer in-depth insights into the applicability of the Precautionary Principle in the context of biotechnology. Further steps forward towards effective operationalisation of this principle under the European legal framework would require the CJEU to elaborate more on questions concerning the employment of the Precautionary Principle.

The question moving forwards relates instead to the implications arising from the trends emerging from the examined decisions. It merits reiterating that the Member States failed to gain the support of the CJEU in all four cases, with each of their precautionary measures to ban GMOs within their territories declared invalid. This was despite the fact that they had attempted to do so by utilising three distinct legal mechanisms to trigger the Precautionary Principle.

The analysis of the four cases suggests that the CJEU tends to favouring international trade over EU policy aim to promote the highest standard of health and environmental protection. This does not echo the *precautionary* European legal and policy framework that should arguably have encouraged the court to take a less narrow approach to evidence regarding risks. To remind us, European States are allowed to take precautionary measures if there are *reasonable grounds* for concern that the potentially dangerous effects on the environment, human, animal or plant health may occur in spite of the presence of insufficient, inconclusive or uncertain scientific evidence.<sup>295</sup> Nevertheless, the strong judicial reliance on scientific knowledge is a common aspect of all four cases, though it ignores the fact that the discussion around GMOs is ridden with scientific uncertainty.<sup>296</sup> This, in turn, mirrors a ‘weak’ expression of the Precautionary Principle, which is in contrast to the ‘moderate/reasonable’ formulation of the Precautionary Principle provided by the European normative framework and the ‘strong’ interpretation of the principle emerging from the *precautionary* European legal and policy framework. As such, this article argues that the CJEU’s rulings are not keeping pace with the European regulatory framework which considers the Precautionary Principle as a key tenet<sup>297</sup> and, through the 2015 Directive, allows Member States to ban GMO cultivation without referring to scientific evidence.<sup>298</sup>

293 This article does not discuss this judgment as it represents a different type of case. For an in-depth analysis of the 2018 judgment, see Felix Beck, *All About That Risk? A (Re-) Assessment of the CJEU’s Reasoning in the “Genome Editing” Case*, 2 EURUP 246–255 (2019).

294 Confédération paysanne and Others, *supra* note 292, para 53.

295 COMM(2000), *supra* note 18, pp 9–10 (emphasis added).

296 Discussions of pros and cons of GMOs can be found in Tenente, *supra* note 5; Pellegrino et al., *supra* note 5; Juma, *supra* note 5; Wiczorek, *supra* note 6.

297 COMM(2000), *supra* note 18, p 12, para 3.

298 The 2015 Directive, *supra* note 9, art 26-b.

The introduction of the 2015 Directive provides for new scenarios under which Member States are allowed to, inter alia, implement domestic precautionary measures aiming to restrict or prohibit the cultivation of GMOs without referring to science-based evidence. The Polish Government took advantage of this opportunity and, in September 2015, 'notified the exclusion of its territory from the possibility of planting any type of modified maize currently admitted to the market for farming in the European Union.'<sup>299</sup> Only a year earlier, the CJEU's had ruled against Poland to banning the cultivation of GMOs on its territory. This illustrates the new opportunities provided for EU Member States by the 2015 Directive.

Thus, the case-analysis invites us to re-think (a) the role of science in legal disputes about issues that are characterized by scientific uncertainty, and (b) the potential role that the Precautionary Principle could play if applied effectively. After all, the CJEU in the 2017 ruling indirectly describes the Precautionary Principle as a suitable legal tool to balance the protection of human health with trade interests, by stating the following:

[T]he conditions set out in Article 54(1) of Regulation No 178/2002, to which the adoption of emergency measures is subject, must be interpreted in the light of, inter alia, the precautionary principle, in order to ensure a high level of protection of human life and health, whilst taking care to ensure the free movement of safe and wholesome food and feed, which is an essential aspect of the internal market.<sup>300</sup>

Finally, while the recent amendments introduced by the 2018 Directive underscore further legislative efforts to develop a more comprehensive ERA for GMOs, they also demonstrate that the legal path towards a more sophisticated and efficient regulation of this technology remains long. Indeed, the complexity surrounding the adverse effects of GMOs can neither be reduced to a quantitative assessment of risk, nor understood mainly through a scientific evaluation of the EFSA. Rather, a path forward with respect to the controversial issue of GMOs requires the adoption of a qualitative evaluation of risk as well as the implementation of judicial decisions tipping the scales in favour of caution. This invites further reflection on how the Precautionary Principle can be better expressed through more detailed guidance in official policies to assist decision-makers, especially because EU policy on GMOs is influenced by external stakeholders. In this respect, the WTO is generally deemed as the most influential external force, having exerted strong pressure to achieve harmonisation of European policies with international standards.<sup>301</sup> Accordingly, the lack of significant steps forward in the European jurisprudence on GMOs can be rationalised as the result of balancing competing internal and external policy interests in cultivating and/or trading GMOs. This would also explain why the jurisprudential path of the CJEU on the Precautionary Principle developed in many contexts, but not in the field of GMOs. This, in turn, might invite the argument that the CJEU, in supporting national requests for cultivating and trading GMOs, is attempting to mitigate the consequences stemming from the fact that

299 I. Wrześniewska-Wal, *Implementation of the CJEU Judgment: An Empty Register*, 13 EUR. FOOD FEED LAW REV. 59, 59 (2018).

300 *Fidenato case*, *supra* note 14, at p 6.

301 Jale Tosun, *How the EU Handles Uncertain Risks: Understanding the Role of the Precautionary Principle*, 20 J. EUR. PUBLIC POLICY 1517, 1522 (2013). See also Grace Skogstad, *Contested Accountability Claims and GMO Regulation in the European Union*, 49 J. COMMON MARK. STUD. 895 (2011).

the European scepticism towards GMOs represents a hurdle for international free trade, as demonstrated by the WTO legal disputes on international trade of GMOs which involve Europe.<sup>302</sup>

Taken together, the findings suggest a fractured legal and policy framework for both the conceptualisation of the Precautionary Principle and regulation of GMOs in the European context. This invites further interdisciplinary research to better understand the capacity of European law to navigate the complex issues raised by GMOs. For instance, considering that the complexity surrounding biotechnology cannot be reduced to a scientific matter, it might be interesting to investigate who should be considered 'expert of GMOs' and, consequently, inform the CJEU about contested biotechnology risks.

#### ACKNOWLEDGMENTS

I am deeply grateful to George F. Tomossy, for his excellent guidance and support. I would also like to extend my gratitude to Professor Shawkat Alam, Dr Aline Jaeckel, and Zara Bending for their valuable feedback on drafts of this research. I also thank Professor and former Justice Carlos Bernal Pulido, for his encouragement in publishing my research. Finally, I would also thank the Reviewers for their thoughtful comments and efforts towards improving my manuscript. I gratefully acknowledge the financial support for this study provided by Macquarie University. All limitations and errors are, of course, my own.

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302 While official positions on GMOs across EU member states are by no means cohesive, anti-GMO sentiment remains strong. This led Ryan-Hume to observe that by October 2015 'around two-thirds of the EU's population—and of its arable land—can be considered GM-free': Joe Ryan-Hume, 'SPICe Briefing—Food for Thought: Scotland & Genetically Modified Organisms (GMOs)', (Research Paper No 15/84, Scottish Parliament Information Centre (SPICe), Parliament of Scotland, 2015) 3–4.