THE PRECAUTIONARY PRINCIPLE AND GENETICALLY MODIFIED ORGANISMS: A BONE OF CONTENTION BETWEEN EUROPEAN INSTITUTIONS AND MEMBER STATES

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Declaration

The work presented in this thesis is, to the best of my knowledge and belief, original except as acknowledged in the text. I hereby declare that I have not submitted this material, either in full or in part, for a higher degree to any other university or institution.

Alessandra Guida
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Sydney, 24 October 2016

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SUMMARY

This dissertation examines how the Precautionary Principle, as an internationally recognised concept enshrined in a range of legal instruments, 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 examines how the European Court of Justice substantively handled the risk assessment phase across three seminal cases between 2003 and 2011 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 products derived from GMOs in their territory. The analysis of these judgements suggests that the Court has applied a narrow approach to the evidence provided by national governments during the risk assessment stage, 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 Court in contrast with the 'strong' interpretation implied by the European legal and policy framework and objections of Member States.

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) represent a prime example of an attempt to address such issues through scientific innovation. A GMO is defined under the European framework[1] as any organism whose genetic material has been artificially altered, which can be achieved through traditional breeding techniques to create hybrid organisms or genetic engineering.[2] Whilst GMOs also provide significant opportunities for trade and commerce, the environmental and human health impacts of introducing or consuming products derived from such organisms cannot be predicted with certainty. Indeed, although there is a lack of unequivocal scientific evidence, numerous studies suggest that GMO usage can lead to serious side effects for health and the environment, such as food allergies, decreased nutritional value, increased toxicity and antibiotic resistance.

The Precautionary Principle is the central concept enshrined by regulatory policies to manage risks to the environment and public health. 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.[3] This thesis aims to improve understanding of the manner in which the Precautionary Principle is applied in the adjudication of legal disputes in relation to GMOs. As Peel observed, however, 'many questions regarding the application of the Precautionary Principle in practice are context-dependent',[4] which invites fuller exposition of the context for this study before setting out the research question.

A. *The Context of GMOs in the European Union*

Public opinion is generally divided between proponents who argue that GMOs offer an essential means to produce more resilient crops with higher yields, and opponents who are

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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] ('*Release of GMOs Directive*').

2 The latter approach relies on the use of scientific techniques, generally referred to as recombinant technology, which artificially transfers functional genes between organisms or species.

3 The Precautionary Principle will be canvassed more fully in Chapter I.

4 Jacqueline Peel, *The Precautionary Principle in Practice: Environmental Decision-Making and Scientific Uncertainty* (The Federation Press, 2005) 6.

concerned with the potentially harmful and irreversible effects of their use.[5] GMOs can thus be popularly viewed as either a benign technology or Pandora's Box.[6] Indeed, Europe is no stranger to this controversy where its approach to the field of genetic manipulation of crops and resulting food products has been characterised in public debates and popular media as a 'Frankenstein' policy, with unequivocal reference to a fear of the consequences of meddling with 'the secrets of life itself.'[7] During the 1990s, European sentiment towards GM foods was so fierce that some politicians were successful in elections by a promise to keep 'Frankenfoods' at bay, continuing to kindle the flame of strong opposition to such products throughout the next decade.[8] While official positions on GMOs across EU member states are by no means cohesive,[9] 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'.[10] Indeed, as will be discussed in Chapter II, an EU Directive issued in 2015 enables EU Member States to ban the cultivation of GM crops (but not the sale of GMO products) within their territory, even in cases where the European Food Safety Authority (EFSA) has issued a positive opinion about the crop.

Public perception has had a significant impact on regulatory policy on GMOs, which varies across jurisdictions to reflect national differences in political culture, risk perception

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5 It should be noted that the debate around GMOs draws upon both scientific and non-scientific studies. Ruth Mampuys and Frans W.A. Brom, 'Governance Strategies for Responding to Alarming Studies on the Safety of GM Crops' (2015) 2(2) *Journal of Responsible Innovation* 201.

6 This dichotomous characterisation of course greatly simplifies more nuanced debates that would emerge from a critical review of the scholarly literature on this topic. It nevertheless reflects the state of *popular* discourse which, as indicated, has nevertheless had a significant impact on European policy governing the cultivation and use of products derived from GMOs.

7 Jesse Male, 'The State of Genetically Engineered Crops in the European Union Following Monsanto v. Italy and the Adoption of a New Regulatory Framework for Genetically Modified Food and Feed' (2004) 9 *Drake Journal of Agricultural Law* 439, 443; John S. Applegate, 'The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms' (2001) 9 *Indiana Journal of Global Legal Studies* 207.

8 This includes the 'white suits' movement, named after the clothes worn by protesters in order to protect themselves from contaminants derived from contact with GMOs, and included acts of sabotage against companies that used GM foods. Applegate, n 7 above 210. Ruby R. Fernandez, 'Monsanto and the Requirement for Real Risks in GM Food Regulation' (2006) 335(28) *Loyola of Los Angeles International and Comparative Law Review* 335, 343; Lizette Alvarez, 'Consumers in Europe Resist Gene-Altered Foods' (2003) *New York Times* 3; Marcel Kuntz, 'Destruction of Public and Governmental Experiments of GMO in Europe' (2012) 3(4) *GM Crops & Food* 258.

9 Jale Tosun and Susumu Shikano, 'GMO-free Regions in Europe: An Analysis of Diffusion Patterns' (2016) 19(6) *Journal of Risk Research* 743, 743-4.

10 For example, Monsanto's maize MON810 (designed to safeguard the crop against a harmful pest) was planted in only five states: Spain (131,537ha), Portugal (8,542 ha), Czech Republic (1,754 ha), Romania (711ha) and Slovakia (411ha). 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.

and tolerance for uncertainty.[11] An analysis of these variables in the European Union (EU) by Wohlers suggested that a perception of 'high threat and low opportunity' held by policy-makers, coupled with a 'fear of the unknown' and 'cautions risk perception' on the part of stakeholders, has led to a framework that is 'elaborate and stringent.'[12] Interestingly, despite this regulatory climate, individual Member States that have sought to ban GMO products have lost all three major cases before the European Court of Justice (ECJ) in 2003, 2007 and 2011, respectively: *Monsanto Italy,*[13] *Austrian case*[14] and *France Monsanto*.[15] In those three cases, as will be elaborated in Chapter III, the ECJ rejected attempts by Italy, Austria and France to trigger the Precautionary Principle to ban GMOs in their territories through three different legal mechanisms respectively: safeguard clauses, derogation from harmonized measures and emergency measures.[16] This outcome calls for an analysis of those cases to gain a deeper understanding of how the ECJ and litigants interpret and apply the Precautionary Principle, as well as to identify the conditions under which a member state might successfully oppose the introduction of GMOs in their territory.

B. *Research Question and Methodology*

Under the European framework for the regulation of GMOs, the ECJ carries out risk analysis[17] in three phases: risk assessment, risk management and risk communication.[18] Under the *European Communication 2000 on the Precautionary Principle*, '[r]ecourse to the principle belongs in the general framework of risk analysis...and more particularly in the context of risk management which corresponds to the decision-making phase.'[19] However,

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[11] Anton E. Wohlers, 'Regulating Genetically Modified Food. Policy Trajectories, Political Culture, and Risk Perception in the U.S., Canada and EU' (2010) 29(2) *Politics and the Life Sciences* 17.

[12] Ibid 32.

[13] *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others* (Case C-236/01) [2003] ECR I-8166 ('*Monsanto Italy'*).

[14] *Land Oberösterreich and Republic of Austria v Commission of the European Communities* (Joined Cases C-439/05 P and C-454/05 P) [2007] ECR I-7185 ('*Austrian case*').

[15] *Monsanto SAS et al v Ministre de l'Agriculture et de la Pêche* (Joined Cases C-58/10 to C-68/10) [2011] ECR I-00000 ('*France Monsanto*').

[16] This outcome might evidence a deeper disconnect between a key EU institution (the ECJ) and member states. However, further exploration of this query crosses over into debates concerning the role of the ECJ in European integration, but falls beyond the scope of this thesis. See, for example, Clifford J. Carruba, Matthew Gabel and Charles Hankla, 'Understanding the Role of the European Court of Justice in European Integration' (2012) 106(1) *The American Political Science Review* 214.

[17] Some authors define risk analysis as "risk governance". See Paul Pechan et al, *Safe or Not Safe: Deciding What Risks to Accept in Our Environment and Food* (Springer, 2011) 12.

[18] Commission of the European Communities*, 'Communication from the Commission on the precautionary principle - COMM(2000)1 final'* (2 February 2000), 2(4) http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52000DC0001&from=EN ('*COMM(2000)*').

[19] Ibid.

litigants provide their arguments during the risk assessment stage, which informs the Court's deliberations in the subsequent risk management stage. Moreover, as revealed by a preliminary review of the key ECJ cases, the risk assessment phase is also the most problematic. The focused question addressed in this thesis, therefore, is: "How has the European Court of Justice substantively handled the risk assessment phase in cases where European Member States have sought to trigger the Precautionary Principle in relation to GMOs between 2003-2011?" Answering this research question invites a doctrinal research methodology, which Hutchinson defined as 'the location and analysis of primary documents of law in order to establish the nature and parameters of the law'.[20] Applied to the current study, after canvassing scholarly approaches to the Precautionary Principle in Chapter I to more fully explain the concept in the European context, Chapter II will identify and analyse the relevant primary legal sources that define the EU regulatory framework for the Precautionary Principle and GMOs, as well as the three seminal decisions by the ECJ in Chapter III. From this analysis, it will be possible to elucidate aspects of the nature and parameters of the current law governing GMOs in the EU in order to identify shortcomings, recommend improvements and delineate areas for further research in Chapter IV.

A doctrinal research methodology is best suited to addressing the research question as stated, which is aimed to serve as a pilot study to better understand the application of the Precautionary Principle in the field of GMOs in legal systems. A doctrinal approach is, however, inherently limited to written sources, and could benefit from qualitative empirical research to survey relevant stakeholders and decision-makers. Such data could provide a very different set of perspectives on how the Precautionary Principle is applied to GMOs to elucidate underlying values or political nuances influencing decision-making. Qualitative research could also complement a law reform research methodology, which through consultation with relevant stakeholders would yield more targeted and evidence-based recommendations for law and policy reform.[21] Such additional research was not undertaken due to time and resource constraints, which situates this study squarely as a precursor for further interdisciplinary research on the topic of the application of the Precautionary Principle in the regulation of GMOs.

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[20] Terry C. Hutchinson, *Researching and Writing in Law* (Thomson, 3rd ed., 2010) 37.
[21] On additional legal research methodologies generally, see Ibid 51-77.

C. *Thesis Structure*

This thesis is divided into four Chapters.

Chapter I will briefly review the concept of the Precautionary Principle, highlighting the underlying failure of scholarship in this area to provide a cohesive rationale for either the principle itself or its implementation during the process of risk analysis. For the purpose grounding subsequent analysis, Chapter I will settle on a broad characterisation of the Precautionary Principle as either 'weak' or 'strong', reflecting the degree to which environmental or health protection is promoted in favour of other objectives. It will also focus attention on 'risk' as the core element of the principle and on the 'risk assessment' phase in risk governance. In conclusion, the first Chapter will situate the role of the Precautionary Principle within the field of GMO regulation in Europe. Chapter I will reinforce the utility of examining case law of the ECJ to gain a better understanding of how EU policy on the Precautionary Principle is applied in judicial decision-making.

Chapter II will set out the European legal framework governing the Precautionary Principle and GMOs necessary to carry out the analysis of ECJ decisions in Chapter III. This will first involve an explanation of the division of competences between the EU and Member States across the key areas of environmental protection, health protection and commerce relevant to GMOs. The Chapter then turns to the evolution of the Precautionary Principle as a legal principle in Europe, followed by an examination of European regulatory framework for GMOs. Two issues will be canvassed in the latter section, namely: a review of problems arising from a 'case-by-case' approach to the assessment of GMOs and a critique of the most recent changes to EU policy on GMOs. Chapter II will also set out the three legal mechanisms through which Member States have sought to trigger a precautionary response to control the cultivation or sale of GMOs within their territories: 'safeguard clauses', 'derogation from a harmonisation measure' and 'emergency measures'. This analysis will shed light on some of the key challenges arising from the legal framework and how these might impact on the ECJ in adjudicating disputes relating to GMOs.

Chapter III will carry out a detailed analysis of the three key judgments of the ECJ between 2003 and 2011 – *Monsanto Italy,*[22] *Austrian case*[23] and *France Monsanto*[24] – to improve understanding of the current state of the law on the regulation of GMOs in Europe.

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[22] *Monsanto Italy* [2003] ECR I-8166.
[23] *Austrian case* [2007] ECR I-7185.
[24] *France Monsanto* [2011] ECR I-00000.

The Chapter will only address those aspects of the cases that relate to the research question, namely how the Court substantively handled the risk assessment phase. From this analysis, it will be possible to draw conclusions about how a narrow approach by the ECJ to evidence about risk during the risk assessment stage 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.

Chapter IV will conclude by setting out key findings that emerge from an analysis across the three cases, shedding light on the current state of the law on the application of the Precautionary Principle to the field of GMOs in Europe. The Chapter will provide some further critical reflections on implications of these findings on the regulation of GMOs in Europe, highlighting the significance of the research and directions for research.

CHAPTER I – THE PRECAUTIONARY PRINCIPLE

In the course of resolving disputes concerning GMOs, the ECJ is expected to render decisions that can have significant economic, environmental or health implications. The Court is challenged to consider potential environmental damages and health hazards even where scientific knowledge of the associated risks is limited. To discharge this task, the ECJ is required to apply the Precautionary Principle in the manner prescribed under the EU legal framework, which will be set out in Chapter II.

Before considering the Precautionary Principle as a legal doctrine, however, it is helpful to have a better conceptual understanding of the principle itself, particularly given the level of attention it has received in scholarship. A full review of the extensive literature on the theoretical and philosophical conceptions of the Precautionary Principle, however, goes beyond the scope of this thesis. This Chapter will examine the Precautionary Principle in three parts. It will first set out a 'weak' or 'strong' characterisation of the principle, against which the pattern of decision-making evidenced by the ECJ in Chapter III can be evaluated. It will then isolate 'risk' as a core element of the principle and focus attention on the 'risk assessment' phase of the process of 'risk analysis' carried out by the Court. This Chapter will conclude by linking the Precautionary Principle to the field of GMOs and European Legal Framework, with some preliminary reflections about the nature of the principle that will carry through to subsequent Chapters.

A. *Characterisation of the Precautionary Principle*

The complexity of the Precautionary Principle has been described by Marchant and Mossman as 'the most innovative, pervasive, and significant new concept in environmental policy over the past quarter century. It may also be the most reckless, arbitrary, and ill-advised.'[25] The Precautionary Principle can be accorded the status of a general legal principal, such as what one might find in criminal law, and not just an algorithm.[26] In contrast, the Precautionary Principle can be seen as merely a form of a policy guidance[27] or a broad guiding principle,[28]

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[25] Gary E. Marchant and Kenneth L. Mossman, *Arbitrary and Capricious: The Precautionary Principle in the European Union Courts* (Washington, DC: American Enterprise Institute, 2004), I.

[26] For example, the principle by which a defendant is innocent until proven guilty beyond reasonable doubt. See Peter T. Saunders and Ho Mae-Wan, 'The Precautionary Principle Is Coherent' (Harvard University, 2000) available at: http://www.cid.harvard.edu/cidbiotech/comments/comments109.htm.

[27] T. Douma Wybe, 'The Precautionary Principle' (European Environmental Law Webpage Dossier) <http://www/eel.nl/virtue/prevprin.htm > 11.

implying that it does not establish exactly when to adopt a precautionary measure but rather encourages policy makers to take this approach.[29] Under an alternative perspective, the Precautionary Principle 'is, in its own right, a crucial scientific tool',[30] although this view can be criticised to suggest that the Precautionary Principle is instead a tool of policy and not of science.[31]

When translated into the legal arena, the different interpretations of the Precautionary Principle can be classified broadly into two categories: 'strong' and 'weak'.

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. The *Wingspread Statement* provides the prime example of a 'strong' interpretation of the Precautionary Principle: 'When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.'[32] An even stronger formulation would require that activities should be prevented unless evidence could show that damage would *not* occur, which would of course be an impossible burden to meet.[33] Indeed, according to some scholars, all strong forms of the Precautionary Principle are seen to be substantially incoherent, with some others referring to 'the precautionary paradox' to denote the contradictory results generated by the application of the Precautionary Principle.[34]

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[28] James Cameron and Juli Abouchar, 'The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment' (1991) 14 *Boston College International and Comparative Law Review* 1.

[29] Jale Tosun, *Risk Regulation in Europe - Assessing the Application of the Precautionary Principle* (SpringerBriefs in Political Science, 2013) 39-40.

[30] Santillo D., R.L. Stringer, P.A. Johnston and J. Tickner, 'The Precautionary Principle: Protecting Against Failures of Scientific Method and Risk Assessment' (1998) 36 *Marine Pollution Bulletin* 939.

[31] Peter M. Chapman, 'Risk Assessment and the Precautionary Principle: A Time and a Place' (1999) 38(10) *Marine Pollution Bulletin* 944.

[32] Steven G. Gilbert, 'Precautionary Principle - The Wingspread Statement' on Toxipedia - connecting science and people (1 December 2010, updated by Maria Mergel 16 March 2016).

[33] Cass R. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge, 2005) 19.

[34] Daniel Steel, *Philosophy and the Precautionary Principle Science, Evidence, and Environmental Policy* (Cambridge University Press, 2015), 21. See also Steve Clarke, 'Future Technologies, Dystopic Futures and the Precautionary Principle' (2005) 7(3) *Ethics and Information Technology* 121; H. Tristram Jr. Engelhardt, Fabrice Jotterand, 'The Precautionary Principle: a Dialectical Reconsideration' (2004) 29(3) *Journal of Medicine and Philosophy* 301; D. Turner and L. Hartzell, 'The Lack of Clarity in the Precautionary Principle' (2004) 13 *Environmental Values* 449; Harris, John, Søren Holm, 'Extending Human Lifespan and the Precautionary Paradox' (2002) 27(3) *Journal of Medicine and Philosophy* 335; Neil A. Manson, 'Formulating the Precautionary Principle' (2002) 24(3) *Environmental Ethics* 263; Indur M. Goklany, *The Precautionary Principle: A Critical Appraisal of Environmental Risk Assessment* (Washington, DC: Cato Institute, 2001); John D. Graham, 'Decision-Analytic Refinements of the Precautionary Principle' (2001) 4 *Journal of Risk Research* 127.

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. For example, Article 15 of the *Rio Declaration* presents what might be 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:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[35]

Criticism of the weak formulation emphasises that potential risks to health and the environment are more likely to be de-emphasised when there is a lack of scientific understanding,[36] and fails to provide detailed requirements for action.[37] However, while there may be a risk in that potentially harmful situations are downplayed in the 'weak' interpretation of the Precautionary Principle, a strong formulation may lend itself to the opposite result by overemphasising potential risks to health and the environment.[38] It is therefore not uncommon to find critiques in the literature of a sharp distinction between 'weak and toothless' and 'strong but unreasonable' formulations of the principle.[39]

Suggestions on how to achieve a better understanding of the Precautionary Principle by scholars also vary. Some authors advocate a middle ground between 'strong' and 'weak' versions.[40] For example, the Precautionary Principle arguably lends itself to three different

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[35] *Rio Declaration on Environment and Development*, 14 June 1992, 31 ILM 874 (1992), Principle 15 ('*Rio Declaration*').

[36] Anne Ingeborg Myhr, 'A Precautionary Approach to Genetically Modified Organisms: Challenges and Implications for Policy and Science' (2010) 23(6) *Journal of Agricultural and Environmental Ethics* 501, 504.

[37] Ibid 504. See also Jonathan B. Wiener and Michael D. Rogers, 'Comparing Precaution in the US and Europe' (2002) 5 *Journal of Risk Research* 317.

[38] Myhr, above n 36, 505. See also Charles Weiss, 'Can There Be Science-Based Precaution?' (2006) 1 *Environmental Research Letters* 1.

[39] Steel, above n 34, 20. See also R. Powell, 'What's the Harm?: An Evolutionary Theoretical Critique of the Precautionary Principle' (2010) 20(2) *Kennedy Institute of Ethics Journal* 181; H. Sterling Burnett, 'Understanding the Precautionary Principle and its Threat to Human Welfare' (2009) 26(2) *Social Philosophy and Policy* 378; Ed Soule, 'The Precautionary Principle and the Regulation of US Food and Drug Safety' (2004) 29(3) *Journal of Medicine and Philosophy* 333.

[40] Myhr, above n 36, 505.

levels of interpretation:[41] first, as it is evaluated in Sweden, the principle can be used to compel governments to adopt a precautionary approach;[42] second, as interpreted in the United Kingdom, it may only allow (but lack the normative force to impose) a precautionary action by governments;[43] and third, as interpreted by the World Trade Organization and the United States, the Precautionary Principle can be considered as a basis for regulatory action during the development of procedural stages of risk analysis.[44]

Others argue that the distinction is misleading and should be replaced with the Precautionary Principle re-conceived as a meta- or a decision-rule.[45] One can also find propositions to qualify the Precautionary Principle by: imposing a *de minimis* condition that could only be triggered when an evidentiary threshold is crossed;[46] considering the context in which risks might eventuate;[47] adding a *minimax* approach that opts for 'the action that minimizes the maximum shortfall from best that could have been achieved';[48] or interpreting the Precautionary Principle through a *maximin* rule.[49] Yet another response to the lack of a unified framework for the Precautionary Principle involves the creation of several Precautionary Principle variants designed for specific circumstances.[50] Finally, due to its undefined boundaries, some authors query whether the existence of *The* Precautionary Principle can be affirmed at all, suggesting that it should be viewed as an approach rather than as a principle[51] – to which the response has been that such a distinction is merely semantic.[52]

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41 Joakim Zander, *The Application of the Precautionary Principle in Practice-Comparative Dimensions* (Cambridge University Press, 2010) 344-5.

42 Jale Tosun, 'How the EU Handles Uncertain Risks: Understanding the Role of the Precautionary Principle' (2013) 20(10) *Journal of European Public Policy* 1517, 1519.

43 Ibid.

44 Ibid.

45 Steel, above n 34, 42-3.

46 Ibid 3. See also Per Sandin, 'Naturalness and De Minimis Risk' (2005) 27(2) *Environmental Ethics* 191; Martin Peterson, 'What Is a *De Minimis* Risk?' (2002) 4 *Risk Management* 47.

47 Steel, above n 34, 3. See also Per Sandin, 'A Paradox Out of Context: Harris and Holm on the Precautionary Principle' (2006) 15(2) *Cambridge Quarterly of Healthcare Ethics* 175.

48 Steel, above n 34, 5.

49 F. Ackerman, *Poisoned for Pennies: The Economics of Toxics and Precaution* (Island Press, 2008); Stephen M. Gardiner, 'A Core Precautionary Principle' (2006) 14(1) *The Journal of Political Philosophy* 33; Sven Ove Hansson, 'The Limits of Precaution' (1997) 2 *Foundations of Science* 293.

50 Lauren Hartzell-Nichols, 'Precaution and Solar Radiation Management' (2012) 15(2) *Ethics, Policy & Environment* 158.

51 Daniel M. Bodansky and Jessica Lawrence, 'Trade and the Environment' in Daniel Bethlehemet al (eds), *Handbook of International Trade Law* (Oxford University Press, 2009). In this regard see Linda O'Neil Coleman, 'Comment - The European Union: An Appropriate Model for a Precautionary Approach?' (2002) 25 *Seattle University Law Review* 609.

52 Ellen Hey, 'The Precautionary Concept in Environmental Policy and Law: Institutionalizing Caution' (1992)4 *Georgetown International Environmental Law Review* 303, 304.

Despite this array of definitional approaches, a straightforward 'weak' or 'strong' distinction will nevertheless be adopted in this thesis to describe any trend that emerges from the analysis of ECJ decisions in Chapter III for the purpose of orienting further research. This approach is considered sufficient, given the focused formulation of the research question and associated research methodology. A more nuanced approach would require a more elaborate and critical examination of the conceptual integrity of the Precautionary Principle than can be achieved within the confines of this study.

B. *'Risk', 'Risk Analysis' and the Precautionary Principle*

Since its inception, the Precautionary Principle has divided scholarly opinion regarding its definition and interpretation.[53] Nevertheless, the primary reason for its introduction remains to safeguard health and the environment from potential risks arising from human action through science, innovation and trade.[54] A set of core elements emerges: [55] (a) the existence of *risk* perceived as a threat of harm, which is the focus of this thesis; (b) the presence *uncertainty* regarding potential effects; and (c) corresponding *action* by stakeholders.[56] The second element of *uncertainty* is an important one, both conceptually as well as legally. It will not be canvassed in this thesis, however, as it falls outside the scope of inquiry defined by the research question. With regard to the third element, *action*, this thesis will examine only the role of the ECJ within the confines of the three identified cases.

As noted by some scholars, the concept of *risk* has had 'quite an impressive career in recent decades',[57] finding its expression in the daily vocabulary of economists, politicians, scientists, philosophers, jurists, and civil society. Beck, who dubbed the term 'risk society', or *Risikogesellschaft*, made the observation that progress leads to choices, which carry

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[53] As shown by Woodman and Klippel, until few years ago, research revolved still around locating a substantial definition of "precaution" or "Precautionary Principle": Woodman Gordon R. and Diethelm Klippel (eds), *Risk and the Law* (Routledge-Cavendish, 2009) 54.

[54] Myhr, above n 36, 504. See also David Kriebel et al., 'The Precautionary Principle in Environmental Science' (2001) 109(9) *Environmental Health Perspectives* 871; Andrew Jordan, 'The Precautionary Principle in the European Union' in Timothy O'Riordan, James Cameron and Andrew Jordan (eds), *Reinterpreting the Precautionary Principle* (Cameron May, London, 2001).

[55] See. eg, Cameron and J. Abouchar, above n 28, 98, who described the three elements as '1) regulatory inaction threatens non-negligible harm; 2) there exists a lack of scientific certainty on the cause and effect relationships; and 3) under these circumstances, regulatory inaction is unjustified.'; and more recently, Trouwborst who states that '[t]he three legs of the precautionary tripod, are (1) a threat of harm, (2) uncertainty, and (3) action.' See Arie Trouwborst, *Precautionary Rights and Duties of States* (Martinus Nijhoff Publishers, 2006) 30; and also, Arie Trouwborst, *Evolution and Status of the Precautionary Principle in International Law* (The Hague, 2002) 51-52.

[56] See especially Trouwborst, 2006, above n 55, 30; Trouwborst, 2002, above n 55, 51-2.

[57] Ingo K. Richter, Sabine Berking and Ralf Müller-Schmid, *Risk Society and the Culture of Precaution* (Palgrave MacMillan, 2006) 1.

unpredictable consequences.[58] 'Risk' has many definitions, including: 'the possibility of adverse effects from some action or event with respect to something that humans value'.[59] It merits noting that, like 'risk', what constitutes an 'adverse effect' and 'value' will vary on a subjective level,[60] such as whether it is perceived by a typical consumer, environmental activist or advocate for a multinational producer.

An attempt can be made to quantify risk through 'the mathematical product of likelihood of occurrence and severity of impact, resulting in a mathematical probability function applied across the range of potential damages'[61] – or, stated in another way, as the product of gravity and probability of harm.[62] Such a formulation allows for a calculation of risk being high where the nature of harm is serious and irreversible, despite a low probability of that harm eventuating.[63]

Despite the vagueness of such a calculus, 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.[64] Drawing upon concepts in natural science, risk governance has three main components: risk assessment, risk management and risk communication.[65] Under the EU framework, this three-stage process is referred to as 'risk analysis' and illustrated in Figure 1 below. [66]

The most pertinent step to the research question in this thesis is the first phase of risk analysis, 'risk assessment' which is located mainly in the scientific domain and defined 'as a tool of gaining knowledge about risks'.[67] The aim in this phase is to quantify and evaluate the probabilities of possible outcomes,[68] providing a mechanism to deal with systemic risks

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58 Ibid.

59 Robert W. Kates, 'Hazard Assessment: Art, Science, and Ideology' in Kates Robert W., Christoph Hohenemser, Jeanne Kasperson (eds), *Perilous Progress: Managing the Hazards of Technology* (Westview Press, 1985) 21; See also Pechan et al, above n 17.

60 Ortwin Renn et al, 'Risks' in Paul Pechan et al, *Safe or Not Safe: Deciding What Risks to Accept in Our Environment and Food* (Springer, 2011) 3.

61 Ibid.

62 J.A. Pascual Trillo, 'Conservación y Gestión Sostenible de los Bosques' in J. Alba Alonso et al (eds), *Nuestros Bosques* (Madrid 1998) 151, 142. See also Trouwborst, 2006, above n 52.

63 Anne Ingeborg Myhr and Terje Traavik, 'The Precautionary Principle: Scientific Uncertainty and Omitted Research in the Context of GMO Use and Release' (2002) 15(1) *Journal of Agricultural and Environmental Ethics* 73, 75.

64 Renn et al, above n 60, 12.

65 Ibid. See also Myhr and Traavik, above n 63; Paul C. Stern and Harvey V. Fineberg, *Understanding Risk - Informing Decisions in a Democratic Society* (National Academy Press, Washington DC, 1996).

66 See above n 18 and accompanying text.

67 Renn et al, above n 60, 13.

68 Myhr and Traavik, above n 63, 74.

facing society.[69] 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';[70] arguing that this phase should be 'solution-focused', requiring understanding of the problem;[71] advocating 'replacement of risk assessment by the precautionary principle';[72] criticising risk assessment as 'part of an advocacy of the strong definition of the precautionary principle';[73] and expressing concerns about the circumstances under which 'risk management depends on the knowledge input from risk assessment'.[74]

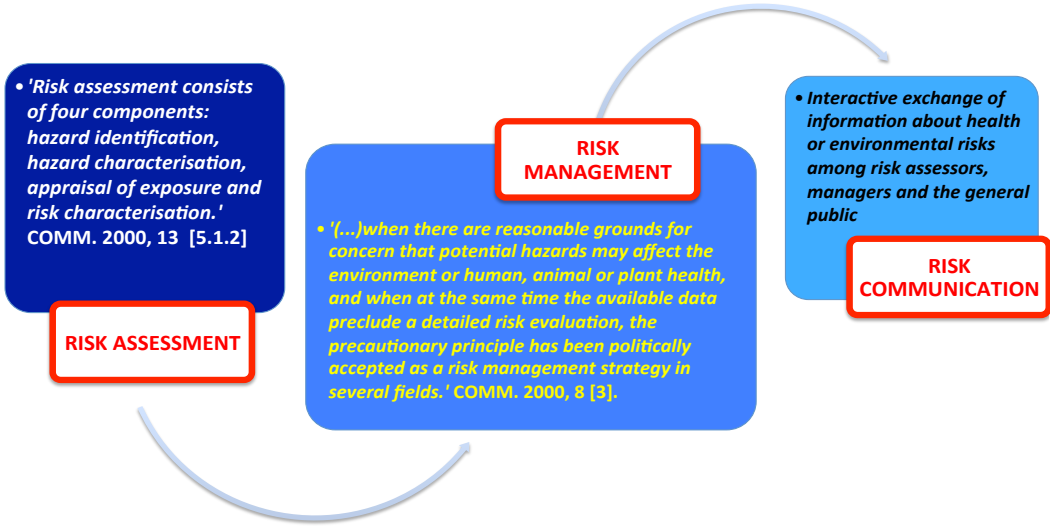

Fig. 1: Risk Analysis stages

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[69] 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.

[70] Terje Aven, 'Foundational Issues in Risk Assessment and Risk Management' (2012) 32(10) *Risk Analysis* 1647.

[71] Bernard D. Goldstein, 'The Culture of Environmental Health Protection: Risk Assessment, Precautionary Principle, Public Health, and Sustainability' (2011) 17(4) *Human and Ecological Risk Assessment: An International Journal* 795.

[72] Ibid 797. See also Adam M. Finkel, '"Solution-Focused Risk Assessment" - A Proposal for the Fusion of Environmental Analysis and Action' (2011) 17 *Human and Ecological Risk Assessment* 754.

[73] Peter Montague, 'Two Friends Debate Risk Assessment and Precaution' on *Rachel's Democracy & Health News* 920 (16 August 2007) <http://www.rachel.org/ q=en/newsletters/rachels_news/print/920#Two-Friends-Debate-Risk-Assessment-and-Precaution>. See also Sheldon Krimsky, 'The Precautionary Approach' (1999) 13(3) *Forum for Applied Research and Public Policy* 34; Carolyn Raffensperger, Ted Schettler and Nancy Myers, 'Precaution: Belief, Regulatory System, and Overarching Principle' (2000) 6(4) *International Journal of Occupational and Environmental Health* 266; Mary O'Brien, *Making Better Environmental Decisions: An Alternative to Risk Assessment* (The MIT Press, Cambridge,2000). See also Goldstein, above n 71, 797.

[74] Renn et al, above n 60, 14.

The third step in risk analysis, represented by 'risk communication', relates to 'bridging the tension between expert judgment and the public perception of risk'.[75] This stage is not addressed in this thesis because, by that point, the shape of the final decision would be well-defined and therefore not relevant to the research question that aims to examine the underlying judicial decision-making process.

Under the European framework, as illustrated in Figure 2 below, the Precautionary Principle falls within the general framework of risk analysis, but is to be 'essentially used by decision-makers in the management of risk'.[76]

'Recourse to the principle belongs in the general framework of risk analysis (...) and more particularly in the context of risk management which corresponds to the decision-making phase.'
(*Summary* COMM. 2000 1 final of 2 February 2000)

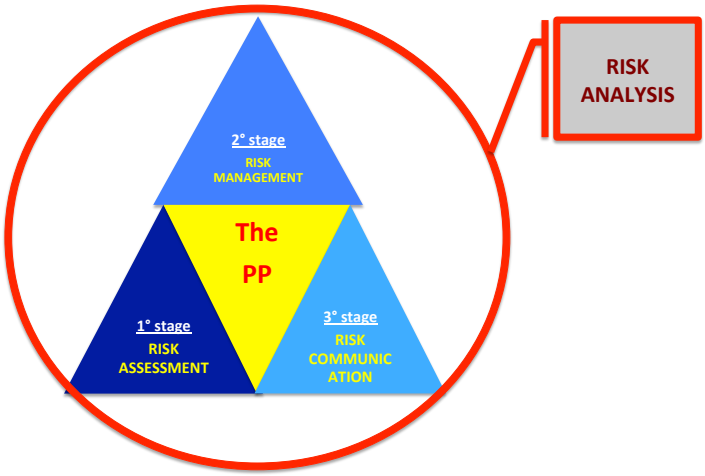

Fig. 2 The Precautionary Principle and Risk Analysis

According to some critics, such an approach prevents the Precautionary Principle from having any useful input into decision-making.[77] Some proponents of GMOs argue to apply the Precautionary Principle at either the risk assessment or risk management stage,[78] while others argue that the Precautionary Principle should only be applied in the risk assessment

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75 Ibid.
76 *COMM(2000)*, above n 18, 2[4].
77 Chauncey Starr, 'The Precautionary Principle Versus Risk Analysis' (2003) 23(1) *Risk Analysis* 1, 3; Pal Wenneras, 'Fog and Acid Rain Drifting From Luxemburg Over Art. 95(4) EC' (2003) 12(6), *European Environmental Law Review* 169. See also the debate reported in the journal *Human and Ecological Risk Assessment* (HERA): Peter M. Chapman 'Does The Precautionary Principle Have A Role in Ecological Risk Assessment?' (1999) 5(5) *Human and Ecological Risk Assessment: An International Journal* 885.
78 Marchant and Mossman, above n 25, 13.

stage.[79] This thesis does not engage with these debates, however, as the aim is to analyse the manner in which the Court has handled the risk assessment phase, and not to critique the underlying policy rationale.[80] The approach prescribed under the EU framework should allow, at least in theory, for a functional evaluation of scientific considerations in the first stage of risk assessment (involving the characterisation and appraisal of hazards or risks) and for societal concerns to be addressed in the second stage of risk management (involving 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').[81]

EU policy on GMOs is influenced by both internal and external stakeholders.[82] The WTO is generally deemed the most influential external force, having exerted strong pressure to achieve harmonisation of European policies with international standards.[83] In terms of internal influence, the EU's policy agenda is influenced by the President of the Council of the EU, which rotates every six months amongst member states granting a chance to influence the European policy according to the national trend of a particular President.[84] However, as the findings in this thesis suggest, policy outcomes can also be influenced by other institutional actors, such as the ECJ through judicial decision-making in the course of its evaluation of expert evidence within the legal process. Assessments of levels of risk and uncertainty provided by the European Commission are made in order to inform the ECJ during the risk assessment phase, and potentially extends the influence of national

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[79] Anne Ingeborg Myhr and Terje Traavik, 'The Precautionary Principle Applied to Deliberate Release of Genetically Modified Organisms (GMOs)' (1999) 11(2) *Microbial Ecology in Health and Disease* 65, 73.

[80] See also Marchant and Mossman, above n 25, 13.

[81] National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (The National Academies Press, Washington DC, 1983), 18-19. See also Peel, above n 4, 146.

[82] Ibid. See also Veenman, Sietske and Duncan Liefferink, 'Different Countries, Different Strategies: "Green" Member States Influencing EU Climate Policy' in Frank Wijen et al (eds), *A Handbook of Globalisation and Environmental Policy, Second Edition - National Government Interventions in a Global Arena* (Edward Elgar Publishing Limited, 2012). Once again, the main cause of these circumstances is due to the undefined context of reference that creates a sort of "state of anarchy" in which all stakeholders - through different legal, economic, political or even social expedients - try to give a reading of the Precautionary Principle Precautionary Principleelements closest to their interests.

[83] Tosun, above n 42, 1522. See also Grace Skogstad, 'Contested Accountability Claims and GMO Regulation in the European Union' (2011) 49(4) *Journal of Common Market Studies* 895.

[84] For further details in this regard, see especially J. Tallberg, 'The Power of the Presidency. Brokerage, Efficiency and Distribution in EU Negotiations' (2004) 42 *Journal of Common Market Studies* 999; A. Warntjen, 'Steering the Union. The Impact of the EU Presidency on Legislative Activity in the Council' (2007) 45 *Journal of Common Market Studies* 1135.

governments through the involvement of nominated national scientific experts.[85] On the other hand, expert risk assessments provided by corporate litigants can also influence judicial decision-makers within an adversarial process of litigation.[86] Understanding how the ECJ substantively handles expert evidence during the risk assessment phase is therefore critical to understanding what evidence is ultimately accepted by the Court to inform its deliberations in the risk management phase where the Precautionary Principle is to be predominantly applied.

C. *Conclusion*

This review of debates surrounding the Precautionary Principle and its place in the process of risk analysis (risk governance) in the European framework indicates a highly fragmented source of legal doctrine.[87] 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.'[88] Whilst this current inquiry 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 thesis should nevertheless improve understanding of how EU policy on GMOs translates (or, alternatively, fails to translate) into to judicial decision-making.

This thesis may thus also help 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. With regard to the latter, however, it is useful to foreshadow that the European regulatory framework on the Precautionary Principle and GMOs set out in Chapter II represents a more coherent point of reference for judicial

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[85] Tosun, above n 42, 1521. See also Markus Haverland, 'How Leader States Influence EU Policy-Making: Analysing the Expert Strategy' (2009) 13 *European Integration online Papers* <http://eiop.or.at/eiop/texte/2009-025a.htm >; M.B.A. Van Asselt and E. Vos, 'Wrestling With Uncertain Risks: EU Regulation of GMOs and the Uncertainty Paradox' (2008) 11 *Journal of Risk Research* 281.

[86] Tosun, above n 42, 1521.

[87] In this regard, it should also be noted that a sizable number of works do not explicitly analyse how the Precautionary Principle affects policy making, how this principle is interpreted by Courts, and the reasoning at the heart of judicial rulings are, nor how application of the Precautionary Principle is influenced by others factors. The bulk of scholarship the issue through a theoretical lens.

[88] *COMM(2000)*, above n 18, 8(3).

decision-making than the conceptual one for the Precautionary Principle generally. For this reason, the analysis carried out in Chapter III will not be based on any theoretical formulation of the Precautionary Principle, but on the provisions contained in the European legal framework would trigger the Precautionary Principle 'only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data.'[89]

[89] *COMM(2000)*, above n 18, 13(5.1.1).

CHAPTER II – THE PRECAUTIONARY PRINCIPLE AND GENETICALLY MODIFIED ORGANISMS UNDER THE EUROPEAN LEGAL FRAMEWORK

As suggested in the preceding Chapter, the European legal framework relating to the Precautionary Principle and GMOs is expected to provide more coherent guidance for the ECJ than can be obtained from more theoretical considerations. However, as will be evident from the analysis of ECJ judgments in Chapter III, this framework presents both procedural and normative dilemmas. Part A will explain the division of power between institutions of the European Union and Member States, which is critical to understanding the central normative conflict between the policy aims to protect the environment and promote a common market. Part B will then set out the key legal instruments establishing the Precautionary Principle as a key tenet of European law. Part C will review the evolution of the legal framework specific to GMOs in Europe in order to elucidate legal principles and some associated challenges that will be relevant to analysing the judgments of the ECJ in Chapter III. The final section will set out the legal mechanisms used by Member States in three seminal cases between 2003 and 2011 delivered by the ECJ to overrule attempts by Member States to trigger the Precautionary Principle to restrict GMOs within their territories.

A. *The European Union*

The European Union is an economic and political union which, in 2016, includes 28 Member States.[90] Its structure includes seven key European Institutions[91] that are assisted by two consultation bodies: the Economic and Social Committee (ESC)[92] and the Committee of the Regions (COR).[93] The *European Council* assumes a key role in expressing the political aims of Europe, with other institutional powers distributed evenly amongst the remaining institutions. The *European Commission* is tasked to propose laws and holds executive power,

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[90] Official website of the European Union, EU member countries < https://europa.eu/european-union/about-eu/countries/member-countries_en>. It should be noted that this number does not factor in the outcome of the recent referendum in the United Kingdom on 23 June 2016 which voted to exit the European Union as formal notice to do so had not yet been submitted nor ratified by British Parliament at the time of writing.

[91] Within the European Union, there are several agencies that represent entities other than the European Institutions. The aims of each agency are different according to the need to develop specific scientific or technical fields or to facilitate dialogue at European and international level.

[92] The main aim of the ESC is to be the voice of different economic and social interests of civil groups of civil society.

[93] The COR expresses the interests of the regional and local authorities of the Member States.

whilst the *Council of EU* and the *European Parliament* comprise the legislative branch.[94] Judicial power has been attributed to the *European Court of Justice,* which is composed of 28 judges (one for each Member State) and supported by 11 general advocates,[95] on which this thesis will focus. The main task of the ECJ is to guarantee that EU laws are properly interpreted and applied in the same manner across Member States.[96]

Power is distributed between the national and European levels through an agreed division of competences provided by the *Treaty of Lisbon*[97] into three main categories:[98]

- *Exclusive competences* where the EU alone is able to legislate and adopt binding acts, which the Member States can implement only if empowered to do so;[99]
- *Shared competences* that allow the European Union and European countries to legislate and adopt legally binding acts jointly;[100] and

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[94] Indeed, the Council of the European Union is the chief decision-maker of Europe that along with the European Parliament has the task to create European laws through the adoption of the propositions submitted by the European Commission.

[95] The European Court of Justice, with its seat in Luxembourg, must not be confused with the European Court of Human Rights with its seat in Strasbourg, the aim of which is to safeguard human rights, or with the International Court of Justice with seat in Hague, whose role is to settle legal disputes brought to its attention by States through advisory opinions in acccordane with the international law. It is also important to underline that every three years a partial replacement of judges and advocates-general takes place: European Council of the European Union, 'Judges appointed to the Court of Justice and the General Court' (Press Release, 649/15, 16 September 2015) < http://www.consilium.europa.eu/press-releases-pdf/2015/9/40802202388_en_635781012000000000.pdf >.

[96] Ibid 7. Due to its role, the ECJ has been referred to as a "legislative watchdog in charge". Strasbourg l'européenne Centre d'Information sur les Institutions Européennes, 'Detailed explanations about the Institutions of the European Union' <http://en.strasbourg-europe.eu/detailed-explanations-about-the-institutions-of-the-european-union,3214,en.html >.

[97] *Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community*, opened for signature 13 December 2007, [2007] OJ C 306/01 (entered into force 1 December 2009) ('*Treaty of Lisbon*').

[98] In order to exercise the EU competences, the European legislator has underlined that the principles of proportionality and subsidiarity have to be respected**.** It should also be said that, in addition to the three main areas of competences, special competences are provided in order to address cases where the EU considers it necessary to take measures to ensure that EU countries coordinate their economic, social and employment policies at EU level.

[99] The areas of exclusive competence are: 1. customs union; 2. the establishment of competition rules necessary for the functioning of the internal market; 3. monetary policy for euro area countries; 4. conservation of marine biological resources under the common fisheries policy; 5. common commercial policy; 6. conclusion of international agreements under certain conditions: Division Of Competences Within The European Union (2016) Eur-lex.europa.eu http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3Aai0020.

[100] The shared areas of competences are: 1. internal market; 2. social policy, but only for aspects specifically defined in the Treaty; 3. economic, social and territorial cohesion (regional policy); 4. agriculture and fisheries (except conservation of marine biological resources); 5. environment; 6. consumer protection; 7. transport; 8. trans-European networks; 9. energy; 10. area of freedom, security and justice; 11. shared safety concerns in public health matters, limited to the aspects defined in the Treaty on the Functioning of the European Union; 12. research, technological development, space; 13. development cooperation and humanitarian aid: Ibid.

- *Supporting competences* through which the EU can only intervene to support, coordinate or complement the action of EU countries where the harmonisation of the adopted measures amongst Member States is not required.[101]

The above division of competences represents one of the most debated aspects of European policy, within which the current topic on GMOs can be seen as emblematic. Indeed, whilst the common commercial policy (which includes trade of GMOs on the European market) is an area of exclusive EU competence, health protection (through which Member States may seek to apply the Precautionary Principle) is an area of supporting competences. Environmental matters fall under the area of shared competences.[102] This demarcation of competences is significant as a Member State's desire to address environmental or public health concerns may come into conflict with broader interests at the level of the European Union, including specifically the aim to promote the circulation of goods within a unified European market. As explained above, the EU can only intervene to support decisions that affect the EU as a whole.

B. *Evolution of the European Legal Framework for the Precautionary Principle*

The first appearance of the Precautionary Principle in the international legal arena is commonly identified as occurring in the 1970s, with some disagreement as to whether Sweden or Germany was the source of origin.[103] The 'precautionary' concept began to take on a more defined shape with its transition in the 1970s from German law, where it arose as the *Vorsorgeprinzip*, to the transnational level, in which it came to be viewed as a useful legal instrument to address firstly the pollution of marine environments, and other environmental issues over the years. From the late 1980s and early 1990s, various international documents[104] adopted the principle, albeit without specific reference to it as a 'Precautionary Principle'. The principle appeared for the first time in 1992 in primary Community Law through the provision of Article 174 of the *Treaty Establishing the European Community*

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[101] The areas related to the supporting competences are: 1. protection and improvement of human health; 2. industry; 3. culture; 4. tourism; 5. education, vocational training, youth and sport; 6. civil protection; 7. administrative cooperation: Ibid.

[102] The conflict between the objective of free circulation of GMOs on the European market (promoted by European Institutions) and protection of human health and the environment (required by Member States) is the central challenge addressed by this thesis.

[103] Peel, above n 4, 16.

[104] *Rio Declaration*; Second International Conference on the Protection of the North Sea (Paper presented at Second International Conference on the Protection of the North Sea, London, 24-25 November 1987); Vienna Convention for the Protection of the Ozone Layer, opened for signature 22 March 1985, 26164 (entered into force 22 September 1988).

('*EC Treaty*'),[105] and is currently enshrined under Article 191 of the *Treaty on the functioning of the European Union* ('*TFEU'*), which prescribes a 'high level of protection' for the environment.[106] The European Union has been at the forefront of adopting and implementing the Precautionary Principle in different areas.[107] European environmental policy aims to achieve a high level of protection,[108] and the TFEU enables Member States to trigger a 'safeguard clause' in order to take provisional measures for environmental protection.

A wide scope of application for the Precautionary Principle was also expressed in February 2000 by the 'Communication from the Commission on the Precautionary Principle' ('COMM(2000)'),[109] which suggested common guidelines for the application of the Precautionary Principle, stressing that it be invoked when the objective scientific assessment concerning a potentially dangerous effect on a phenomenon, product or process did not allow a sufficiently reliable determination of risk. The intention was to set a precautionary approach as the starting point for all European regulations affecting health and the environment as illustrated in Figure 3 below.

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[105] *Treaty Establishing the European Community*, opened for signature 7 February 1992, [1992] OJ C 224/6 (entered into force 1 November 1993) ('*EC Treaty'*). Article 174 prescribes that Community policy shall contribute to the pursuit of objectives that include: 'preserving, protecting and improving the quality of the environment'; 'protecting human health'; 'prudent and rational utilisation of natural resources'; and 'promoting measure at international level to deal with regional or worldwide environmental problems'.

[106] *Treaty on the Functioning of the European Union*, opened for signature 7 February 1992, [2009] OJ C 115/199 (entered into force 1 November 1993) ('FEU'). See also Stuart Bell, Donald McGillivray, Ole Pedersen, *Environmental Law – Eighth Edition* (OUP Oxford, 2013) 72.

[107] Marchant and Mossman, above n 25, 6. Although the Precautionary Principle Precautionary Principle has been referred to under Community Food Law since the mid-1990s, the Precautionary Principle was formally established in food legislation through Article 7 of Regulation 178/2002 on General Principles of Food Law: *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 ('*Food Law Regulation*').

[108] With Article 191 TFEU, the Precautionary Principle has been added to the list of Environmental principles.

[109] *COMM(2000)*, above n 18.

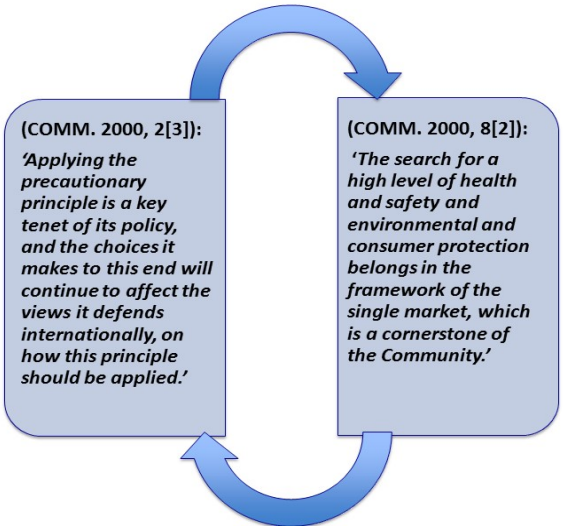

Fig. 3: Relevance given by the European Legislator to the Precautionary Principle

COMM(2000) reinforces the Precautionary Principle as a key concept of the policy framework for the European Community. Indeed, recourse to the Precautionary Principle has been defined as 'a central plank of Community policy.'[110] Moreover, it has been stated that, even if the Community can establish a level of protection that it deems appropriate, application of the Precautionary Principle should be considered 'a key tenet of its policy'.[111] However, the aim to promote a 'high level' of health and safety environmental protection and consumer protection is also to be interpreted within a framework intended to create a single market, which may not be sympathetic to state-by-state implementation of the Precautionary Principle to limit commercial activity within national territories.

Despite the effort to provide this important guidance, COMM(2000) has not made satisfactory progress in clarifying the Precautionary Principle further, and failed to answer many vital questions about its meaning. Although the concept of risk represents a central parameter for Member States to activate safeguard measures, COMM(2000) fails to clarify what level of risk should be considered acceptable. As foreshadowed in Chapter I, a further peculiar aspect of COMM(2000) concerns the role afforded to the Precautionary Principle within the *process* of risk analysis, specifying that, although the Precautionary Principle

[110] COMM(2000), above n 18, 12.
[111] COMM(2000), above n 18, 2(3).

belongs to a general framework of risk analysis,[112] it is most relevant at the stage of risk management.[113] In this regard, the European legislator has underscored the importance of not confusing the Precautionary Principle (used by decision-makers in the management of risk) and the element of *caution* (applied by scientists during their evaluation of scientific data).[114] Authorities are expect to make a decision during the risk management stage only *after* the level of risk has been assessed on the basis of scientific findings. As the analysis in Chapter III will demonstrate, these issues emerge as important factors influencing the decision-making of the ECJ.

Nevertheless, it should be noted that COMM(2000) suggests ways to improve understanding of the Precautionary Principle in Europe. Specifically, it proposes that the principle should be examined not only in legislative texts, but also in the case law of the ECJ and any Court of First Instance because 'they have already had occasion to review the application of the precautionary principle (…) develop(ing) case law in this area.'[115] The European Courts have therefore, to a certain extent, filled that policy vacuum.[116] The following sections will thus analyse the evolution of the European legislative framework for GMOs, and also set out the mechanisms by which Member States can trigger the Precautionary Principle to restrict GMOs within their territories.

C. *The Legal Landscape for GMOs in Europe*

Since 1980, with the introduction of the first genetically modified plants, commercial applications for genetic engineering have evolved quickly on an international scale. Between 1990 and 1997, the public debate on GMOs was high on the political agenda of Member

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[112] 'Risk Analysis' – defined by some scholars as 'Risk Governance', as explained in the previous Chapter – is comprised of three different steps: risk assessment, risk management and risk communication. Annex III explains how risk assessment consists of four components – hazard identification, hazard characterisation, appraisal of exposure and risk characterisation – which can be strongly influenced by the limits of scientific knowledge.

[113] COMM(2000), above n 18, 2.

[114] Ibid. Moreover, as provided for in all risk management measures, COMM(2000) underscores the importance of compliance with general principles when a measure has been adopted in light of the Precautionary Principle. According to the para. 6.3 of COMM(2000), above n. 18, these general principles include: proportionality, non-discrimination, consistency, examination of the benefits and costs of action or lack of action, and examination of scientific developments. Moreover, When the Precautionary Principle is invoked, European provisions regarding the burden of proof deserve particular attention. Whilst in the majority of the cases the European consumer must demonstrate the danger associated with a product placed on the market, in a case where the action has triggered the Precautionary Principle, the producer should prove the absence of danger.

[115] Ibid, 8-9.

[116] Lofstedt Ragnar, 'The Precautionary Principle in the EU: Why a Formal Review is Long Overdue' (2014) 16(3) *Risk Management* 137, 145.

States in the European Union, particularly because many refused to authorize the introduction of GM products on their market by invoking the so-called 'safeguard clauses'.[117] To overcome this trend of denial by most Member States, Europe embarked on the hard path of rewriting of the regulatory framework.[118]

The first steps were taken with the promulgation of Directive 90/220/EEC,[119] which was grounded in a case-by-case approach and preventive principle.[120] This was the first Community measure to regulate the deliberate release of GMOs into the environment. This Directive more firmly established the role of the Precautionary Principle, made more decisive by its explicit introduction into the *EC Treaty*,[121] and signalled its later prominence.[122] The complexity of the requirements applied to the approvals of GMOs resulting from Directive 90/220/EEC,[123] however, earned it the label of a 'Gordian knot',[124] which when compounded by several associated inconsistencies led to replacement of that Directive on 17 October 2002 with Directive 2001/18/EC.[125]

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

(i) Protect human and animal health and the environment before any GMO is placed on the market;
(ii) Put in place harmonised procedures for risk assessment and authorisation of GMOs; and

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[117] In April 2011 there were 22 active bans in place across six Member States: Austria, France, Germany, Luxembourg, Greece, and Hungary. See Maite Sabalza et al, 'EU Legitimizes GM Crop Exclusion Zones' (2011) 29 *Nature Biotechnology* 315. Thus, over the following years, several Member States, led by France, voted for a block of authorizations for GMOs on the European market until the introduction of appropriate labelling rules in order to guarantee the right of an informed choice to European citizens, and for a general review of the European legislation in light of the Precautionary Principle. As result, from 1998 to 2004, no new GMOs were authorized in the EU.

[118] Given the internal market dimension, the European legislator has based the legislative framework of GMOs on '(…) a high level of protection (…) based on the precautionary principle and on the principles that preventive action should be taken (...)': *Treaty Establishing the European Community*, above n 105*,* art. 130 r (2).

[119] *Council Directive 90/220/EEC of 23 April 1990 on the Deliberate Release into the Environment of Genetically Modified Organisms* [1990] OJ L 117/1.

[120] R. MacKenzie and S. Francescon, 'The Regulation of Genetically Modified Foods in the European Union: An Overview' (2000) 8(3) *New York University Environmental Law Journal* 530, 533.

[121] *Treaty Establishing the European Community*, art 174.

[122] Directive 90/2002/EEC tried, in particular, to balance the needs of Member States to maintain some decision-making control about internal concerns in the field of genetic engineering with the necessity of the European Institutions to harmonize domestic regulations in order to safeguard the free circulation of GMOs.

[123] *Release of GMOs Directive* [1990] OJ L 117/1.

[124] See Joël Andriantsimbazovina, 'Le CE et le Principe de Précaution, L'affaire du Maïs Transgénique' (1999) 6 *Droit Administrative* 4.

[125] Through the adoption of the latter directive, the European Union has established a legal framework that aims to find a balance between the development of modern biotechnology - with specific reference to GMOs - and the provision of necessary safe conditions regarding these new organisms - due to their potential harmful effects on health and the environment.

(iii)Ensure clear labelling and traceability of GMOs placed on the market.[126]

In order to achieve these goals, Europe has provided as 'building blocks of the GMO legislation'[127]five legislative pillars represented by three European Directives[128] and two European Regulations,[129] and has implemented several rules and recommendations on more specific aspects.

1 *Problems with the 'case-by-case' Assessment of GMOs*

Directive 2001/18/EC[130] replaced the previous Directive 90/220 'for reasons of clarity and rationalisation'.[131] Through this Directive, the European legislator expressly set out a legislative framework for a precautionary approach[132] 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 'green' intention of the European Legislator to consider the Precautionary Principle as 'a central plank of Community policy',[133] a number of provisions, as demonstrated by their implementation by the ECJ in Chapter III, effectively serve to impair the Precautionary Principle from achieving its potential under the European regulatory framework.

The EC legislation provides, on the basis of international standards, that the risk assessment approach for GMOs is to be carried out on *case-by-case* analysis.[134] This implies that any GMO must be assessed by the competent authorities on its individual merits, namely by addressing 'each individual combination of a new gene coding for a particular character

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[126] European Commission, 'GMO legislation', < http://ec.europa.eu/food/plant/gmo/legislation/index_en.htm >.
[127] Ibid.
[128] *Release of GMOs Directive* [2001] OJ L 106/1, 2(2); *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 ('*Cultivation of GMOs Directive*'); *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.
[129] *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 ('*GMO Regulation*); *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.
[130] *Release of GMOs Directive* [2001] OJ L 106/1, 2(2).
[131] Ibid Preamble para 3.
[132] Ibid art 4(1).
[133] *COMM(2000)* 12.
[134] Ibid Preamble paras 18-19, art 4(3). Through the provision of Preamble 24 para 2, the case-by-case approach is also defined the 'step-by-step' principle.

with a specific host organism, for each use.'[135] Thus, the European framework does not provide for risk assessment that covers any and all biotechnology products, and does not support a broad 'moratorium on any and all biotech products'.[136] Nevertheless, as can be seen from the cases reviewed in Chapter III, the ECJ will still ask national governments to carry out risk assessment as completely as possible.

A further dilemma posed by a narrow approach relates to the extrapolation of GMOs from one context to another – i.e. from laboratory to commercial scale – which raises unresolved questions concerning the environmental impact of GMOs within a real-world context.[137] Indeed, 'while small scale trials are limited by size and management, the commercial release involves a major number of GMOs to be released', and more complex ecosystems to consider.[138] Through a limited approach, it is also not possible to consider that the harmful effects of GMOs that can evolve slowly and through long chains of effects, and that in most cases these effects cannot be captured in small trials.[139]

Another controversial point concerns the assessment of products that have already been subjected to prior applications. Preamble 17 of Directive 2001/18/EC emphasises that GMOs 'which have conventionally been used in a number of applications and have a long safety record'[140] are not subject to the application of provisions laid down by the same Directive.[141] This problem for Member States emerges clearly in *Monsanto France*,[142] which will be analysed in Chapter III, insofar as the European provision conflicts with the ECJ's request to the Member State to carry out of a risk assessment as completely as possible.

A final example was highlighted by *Monsanto Italy*,[143] also analysed in Chapter III, and concerns the European provision on substantial equivalence between GM products and

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[135] World Trade Organization, *Dispute Settlement Reports 2006: Volume 6, Pages 2243-2766* (Cambridge University Press, 21 February 2008).
[136] Ibid.
[137] Myhr and Traavik, above n 63, 79; See also L.L. Wolfenbarger and P.R. Phifer, 'The Ecological Risks and Benefits of Genetically Engineered Plants' (2000) 290 *Science* 2088.
[138] Myhr and Traavik, above n 63, 79.
[139] Ibid.
[140] *Release of GMOs Directive* [2001] OJ L 106/1, Preamble para 17.
[141] In fact, as provided by the following art. 23, the reassessment of GM products is allowed only when new scientific knowledge suggest their potential harmful effects.[141]
[142] *France Monsanto* [2011] ECR I-00000. Indeed, it can be noted in that case that GM maize MON 810 was authorized by the Directive 90/220, which was no longer in force, and then notified by Monsanto to the Commission as an 'existing product' without reassessing the product under the new standards laid down by Directive 2001/18/EC (which replaced the Directive 90/220/EEC).
[143] *Monsanto Italy* [2003] ECR I-8166.

traditional foods. In that case, Regulation No 258/97/EC[144] relies on 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.[145] 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.'[146] However, as suggested by Advocate General A.G. Alber in his opinion regarding *Monsanto Italy,*[147] 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.[148]

2 *Article 26-b Directive 2001/18/EC*

Although occurring outside the timeframe of cases that will be analysed in Chapter III, a few additional developments merit mention in order to have a full understanding of the current state of play for the regulation of GMOs in Europe.

In the face of ongoing public opposition to GMOs, 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.[149]

Instead of this negotiated approach, Directive (EU) 2015/412 introduced a new

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[144] *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 ('*Novel Foods Regulation*').

[145] According to Article 1(2), there are six categories of novel foods and food ingredients to which the provisions of Regulation 258/97 apply; however, the first two – (a) foods and food ingredients containing or consisting of genetically modified organisms, and (b) foods and food ingredients produced from, but not containing, genetically modified organisms – have been removed from its scope by Regulation No 1829/2003/EC. In addition, Article 2 of Regulation (EC) No 258/97 underlines that the provisions of the Regulation do not applied to (a) food additives, (b) flavourings for use in foodstuffs, and (c) extraction solvents used in the production of foodstuffs.

[146] *Novel Foods Regulation* [1997] OJ L 43/1, art 3 (4).

[147] *Monsanto Italy* [2003] ECR I-8166.

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

[149] Paul 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) <http://www.intlcorn.com/seedsiteblog/?p=358>; Tosun, above n 29, 72-73.

Article 26-b into Directive 2001/18/EC, which provides 'the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory'.[150] 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 undermines any purported intention on the part of European Institutions to empower Member States. Firstly, any domestic provision by a Member State made under Article 26-b must be proportional and non-discriminatory, and enacted on the basis of 'compelling grounds'.[151] Secondly, the amendment expressly refers to the *cultivation* of GMOs, excluding the question of trade (and consequent import) of GMO foodstuffs. It should be noted that the Commission proposed that the amendment also provide for the trade of GMOs, giving 'the last word' to Member States. However, the European Parliament contested this proposition, and consequently rejected that proposal because it was deemed to be 'impracticable' for its socio-economic impacts.[152] This recent amendment, therefore, can be seen as clumsy attempt by European Institutions to mollify Member States while leaving fundamental problems associated with the regulation of GMOs unresolved.

D. *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 three cases analysed in Chapter 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*[153] and *France Monsanto,*[154] drawing upon two distinct legal instruments: Article 12 of Regulation No 258/97[155] and Article 23 of Directive 2001/18/EC; [156]
- a 'derogation from a harmonisation measure', employed in the *Austrian case,*[157] based on Article 95(5) of the *EC Treaty*; and

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[150] *Cultivation of GMOs Directive* [2001] OJ L 68/1.
[151] Ibid art 26-b (3).
[152] 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, 17.
[153] *Monsanto Italy* [2003] ECR I-8166.
[154] *France Monsanto* [2011] ECR I-00000.
[155] *Novel Foods Regulation* [1997] OJ L 43/1, art 12.
[156] *Release of GMOs Directive* [2001] OJ L 106/1, art 23.
[157] *Austrian case* [2007] ECR I-7185.

- an 'emergency measure', applied in *France Monsanto,*[158] under Article 34 of Regulation No 1829/2003/EC.[159]

Other general measures can be adopted to invoke the Precautionary Principle; however, this thesis will limit discussion to only those mechanisms considered by the ECJ in the judgments analysed in Chapter III.

1 *'Safeguard Clauses': Article 12 Regulation No 258/97/EC and Article 23 of Directive 2001/18/EC*

Regulation No 258/97 concerns novel foods and novel food ingredients in the European market.[160] Article 12 of that Regulation, employed in *Monsanto Italy,*[161] 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 'endangers human health or the environment'.[162] This view can arise from either 'new information or a reassessment of existing information'.[163]

Directive 2001/18/EC concerns the deliberate release of GMOs into the environment.[164] Article 23 of that Directive, applied in *Monsanto Italy,*[165] 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'.[166] 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.[167] The view to restrict or prohibit the product must be as a result of either: 'new or 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'.[168]

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[158] *France Monsanto* [2011] ECR I-00000.
[159] *GMO Regulation* [2003] OJ L 268/1, art 34.
[160] *Novel Foods Regulation* [1997] OJ L 43/1.
[161] *Monsanto Italy* [2003] ECR I-8166.
[162] *Novel Foods Regulation* [1997] OJ L 43/1, art 12 states:
> A Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory.

[163] Ibid.
[164] *Release of GMOs Directive* [2001] OJ L 106/1, art 23.
[165] *Monsanto Italy* [2003] ECR I-8166.
[166] *Release of GMOs Directive* [2001] OJ L 106/1, art 23.
[167] Ibid arts 13-19.
[168] Ibid.

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.[169]

2 *'Derogation from a Harmonization Measure': Article 95(5) of the EC Treaty*

Article 95(5) of the *EC Treaty*,[170] employed in the *Austrian case,*[171] 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 problem specific to that Member State arising after the adoption of the harmonisation measure'.[172] 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'.[173]

3 *'Emergency Measure': Article 34 of Regulation No 1829/2003*

Regulation No 1829/2003 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.[174] Article 34 of that Regulation, employed in *France Monsanto,*[175] 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

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[169] The Commission is required to make a decision 'as soon as possible' pursuant to Article 12 of *Novel Foods Regulation* [1997] OJ L 43/1 and 'within 60 days', calculated as set out, under Article 23(2) of *Release of GMOs Directive* [2001] OJ L 106/1.

[170] Article 95(5) of the *EC Treaty* provides that:

> If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

[171] *Austrian case* [2007] ECR I-7185.

[172] *EC Treaty,* art 95(5).

[173] Ibid art 6.

[174] *GMO Regulation* [2003] OJ L 268/1, art 1.

[175] *France Monsanto* [2011] ECR I-00000.

the environment' or where an urgent need to do so arises from an opinion issued by the European Food Safety Authority.[176] Procedural requirements are set out in Articles 53 and 54 of Regulation No 1829/2003,[177] 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 Chapter III.

E. *Conclusion*

The review of the European regulatory framework in this Chapter highlights a number of challenges for the ECJ to carry out its task to adjudicate disputes regarding GMOs, as well as for litigants. In particular, the European framework clearly directs that the Precautionary Principle is to be applied fundamentally in the second phase of risk analysis (risk management) rather than the first phase (risk assessment). This rule would preclude litigants from applying the Precautionary Principle during the risk assessment phase, and further inhibit the capacity of Member States to apply a higher level of protection for health and the environment than is provided for by the European Community. This limitation also infringes upon the right of Member States to independently introduce measures for health as provided by the agreed division of competences under the *Treaty of Lisbon*.

Further, a strict interpretation of evidentiary considerations could exacerbate (as it in fact does, as shown in Chapter III) the impact of excluding evidence put forward by Member States during the risk analysis stage, thereby in a sense pre-empting the outcome of the application of the Precautionary Principle during the risk management stage.

Finally, the ECJ must grapple with gaps in the legal framework that relate to: inadequacies arising from the case-by-case approach,[178] due to its failure to consider the longer time-frame required to assess potential harmful impact of GMOs on health and the environment; and a lack of more directed guidance on how to carry out the process of risk assessment.

Chapter III will now carry out a detailed analysis of the three seminal cases handed down by the ECJ between 2003 and 2011. The results of that analysis will corroborate the shortcomings of the European Legal Framework to regulate GMOs noted above, as well as shed light on further controversial elements. Chapter III will also analyse those cases in light

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[176] *GMO Regulation* [2003] OJ L 268/1, art 34.
[177] *Food Law Regulation* [2002] OJ L 244/1, arts 53-54.
[178] *Release of GMOs Directive* [2001] OJ L 106/1.

of the conceptual review of the Precautionary Principle carried out in Chapter I, allowing for findings to be made in relation to both the legal and conceptual foundations of the Precautionary Principle and for the review of GMOs by the ECJ in Europe.

CHAPTER III – THE PRECAUTIONARY PRINCIPLE AND GENETICALLY MODIFIED ORGANISMS: ANALYSIS OF THREE SEMINAL CASES OF THE EUROPEAN COURT OF JUSTICE (2003 – 2011)

Having canvassed relevant conceptual considerations relating to the Precautionary Principle and European legal framework for the regulation of GMOs in the first two Chapters, this Chapter will now undertake a legal doctrinal analysis of the three seminal judgments concerning GMOs rendered by the ECJ between 2003 and 2011: *Monsanto Italy*,[179] *Austrian case*[180] and *France Monsanto.*[181] Across these three cases, Member States unsuccessfully attempted to trigger the Precautionary Principle to sustain bans of GMOs through the three distinct legal mechanisms set out in Chapter II and illustrated in Figure 4 below. This analysis will shed further light on problems with the European legal framework and conceptualisation of the Precautionary Principle.

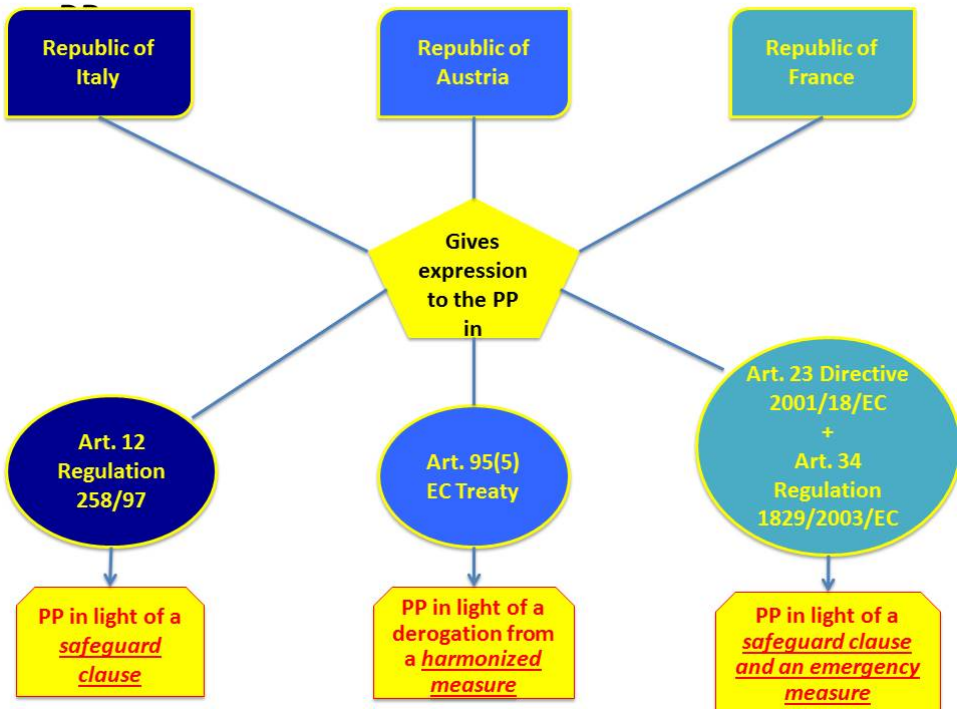

Fig. 4: Precautionary Principle triggered by Italy, Austria and France

[179] *Monsanto Italy* [2003] ECR I-8166.
[180] *Austrian case* [2007] ECR I-7185.
[181] *France Monsanto* [2011] ECR I-00000.

Monsanto Italy[182] is one of the first judgments concerning the application of the Precautionary Principle to the trade of new GM maize lines submitted to the attention of the ECJ. In 2003, the Italian Government triggered a provision to temporarily suspend trade in the use of the maize line on the basis that it 'endangers human health or the environment'.[183] The analysis of that case will revolve around two key issues: the determination of 'substantial equivalence' between novel and existing foods or food products, which is a pre-cursor to being able to bring GMOs onto the market through a 'simplified procedure'; and legitimacy of a national precautionary measure adopted in light of a 'safeguard clause' under Article 12 of Regulation 258/97.

Four years later, through the *Austrian case,*[184] the Republic of Austria provided notice to the European Commission about a draft law of the Land Oberösterreich (Upper Austria) banning the cultivation of seed and planting material composed of or containing GMOs and the breeding and release of transgenic animals. This ban was based on Article 95(5) of the EC Treaty as a derogation of a harmonisation measure on the basis of 'new scientific evidence relating to the protection of the environment'.[185] Of the four issues pleaded by the applicants (Republic of Austria and Land Oberösterreich) only the issues relating to the infringement of the EC Treaty and breach of the Precautionary Principle will be analysed.

Finally, in 2011 with *France Monsanto*,[186] France referred to two 'umbrella regulations'[187] that governed genetically modified agricultural plants in order to suspend the authorisation for transfer and use of MON 810 maize seed in its territory. The French Government justified the ban by invoking the Precautionary Principle through both a 'safeguard clause' provided by Article 23 Directive 2001/18/EC[188] and 'emergency measure' pursuant to Article 34 Regulation No 1829/2003/EC.[189] The analysis of this last judgment will address issues relating to the legal adoption of unilateral measures by Member States and the conditions for the adoption of emergency measures in light of the Precautionary Principle.

These three cases will be systematically analysed by setting out: (a) the background to the dispute; (b) legal reasoning of the litigants and Court's deliberations (c) the Court's ruling

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[182] *Monsanto Italy* [2003] ECR I-8166.
[183] *Novel Foods Regulation* [1997] OJ L 43/1, art 12.
[184] *Austrian case* [2007] ECR I-7185.
[185] *EC Treaty*, art 95(5).
[186] *France Monsanto* [2011] ECR I-00000.
[187] *Release of GMOs Directive* [2001] OJ L 106/1; *GMO Regulation* [2003] OJ L 268/1.
[188] *Release of GMOs Directive* [2001] OJ L 106/1, art 23.
[189] *GMO Regulation* [2003] OJ L 268/1, art 34.

in relation to the key issues; and (d) a concluding analysis with specific findings. In accordance with the formulation of the research question, specific attention will be afforded to how the risk assessment stage is substantively handled by the Court and how this impacts on the application of the Precautionary Principle. Final recommendations, including linkages across to the conceptual elements of the Precautionary Principle from Chapter I and legal framework from Chapter II, will be set out in Chapter IV.

A. *Monsanto Italy 2003: The Precautionary Principle in Light of a Safeguard Clause*

1 *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[190] (hereinafter *"novel foods"* or "*novel foodstuffs"*) on the market. This notification was required under Article 5 of Regulation 258/97/EC[191] 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'.[192]

The Italian Health Ministry, through a long period of correspondence with the Commission (November 1998 to July 2000), 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.[193] 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

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[190] Specifically, maize lines Bt-11, MON 810 and MON 809.

[191] *Novel Foods Regulation* [1997] OJ L 43/1, art 5 states: *'In the case of the foods or food ingredients referred to in Article 3 (4), the applicant shall notify the Commission of the placing on the market when he does so*, Regulation No 258/97/EC has been amended by Art. 38 of Regulation No 1829/2003/EC, which has considerably reduced its scope. Nevertheless, it is still the most important normative reference of novel foods.

[192] *Monsanto Italy* [2003] ECR I-8166, I-8182 [19].

[193] When a novel food or food ingredient has been considered substantially equivalent to a traditional one, it may be placed on the market with a mere notification of this decision to the Commission by the applicant after observing all additional conditions of the *Novel Foods Regulation* [1997] OJ L 43/1.

protective safeguard measures under Regulation 258/97,[194] adopted a Decree to suspend trade in and use of the novel foods within Italy.[195]

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,[196] 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,[197] 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.[198]

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 as a result of the ban.[199] In the circumstances, the TAR stayed the proceedings and submitted questions to the ECJ for a preliminary ruling.[200]

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 ECJ: (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.

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[194] *Novel Foods Regulation* [1997] OJ L 43/1, art 12. Indeed, according to the first paragraph of Article 12: '[w]here a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision.'

[195] *Monsanto Italy* [2003] ECR I-8166, I-8184 [31].

[196] *Novel Foods Regulation* [1997] OJ L 43/1, art 11 states: 'The Scientific Committee for Food shall be consulted on any matter falling within the scope of this Regulation likely to have an effect on public health.'

[197] *Monsanto Italy* [2003] ECR I-8166, I-8185 [35].

[198] Ibid I-8185 [36], I-8186 [39].

[199] Ibid I-8186 [40].

[200] Ibid I-8188 [48].

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

a) 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.[201] This represents a decisive step 'based on considerations arising from prudence and the development of scientific knowledge'.[202] Since Monsanto's notification had been given prior to reaching that agreement, the ECJ 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 followed a different direction. The companies 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[203] 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. In particular, as explained by Advocate General Alber, '(s)ince it is not disputed that the remaining traces of transgenic protein are not genetically modified organisms, only substantial equivalence is at issue'.[204]

Taking a different view, 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 an aim of Regulation No 258/97 to safeguard public health.[205] The Italian Government referred to Part

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[201] Ibid I-8182 [21].
[202] Ibid I-8194 [66].
[203] *Novel Foods Regulation* [1997] OJ L 43/1.
[204] Opinion of Advocate General Alber, above n 148, I-8124 [35].
[205] *Monsanto Italy* [2003] ECR I-8166, I-8191 [53].

I, Section 3, point 3.3 of the Annex to Recommendation 97/618/EC[206], 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 (composition, nutritional value, and so forth)'.[207] It also added that the presence of transgenic proteins resulting from inserted genes, as observed in the main proceedings by the *Istituto superiore di sanità* (Italian Federal Board of Health), 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.[208] The Norwegian Government supported this line of reasoning, arguing that a more detailed assessment should be carried out as part of a comprehensive risk assessment, especially because the insertion of foreign genes can give rise to unknown effects on the composition of a plant.[209]

Throughout the judgment, the ECJ refers 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,[210] and to safeguard public health against the resultant risks.[211] 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.[212]

The ECJ determined that the definition of substantial equivalence provided by Recommendation 97/618/EC[213] 'does not in itself involve a safety assessment, but rather constitutes an approach for comparing the novel food with its conventional counterpart in order to determine whether it should be subject to a risk assessment (…)'.[214] The Court added that the concept of substantial equivalence should be contextualised through the work of international scientific institutions. It asserted that the absence of substantial equivalence does

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[206] *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*').
[207] *Monsanto Italy* [2003] ECR I-8166, I-8191 [54].
[208] Ibid I-8191 [55].
[209] Ibid I-8192 [58].
[210] *Novel Foods Regulation* [1997] OJ L 43/1, Preamble.
[211] Ibid Preamble, art 3(1).
[212] *Monsanto Italy* [2003] ECR I-8166, I-8196 [73]–[74].
[213] *Recommendation on Novel Foods* [1997] OJ L 253/1, 5.
[214] *Monsanto Italy* [2003] ECR I-8166, I-8197 [77].

not necessarily imply that the foods in question are unsafe, but merely that they should be subject to an assessment about their potential risks.[215]

With reference to the observations made by TAR regarding the fast track procedure, 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.'[216]

Finally, in response to the considerations put forward by the Norwegian Government, the Court emphasised that 'if such [contested] effects [of foodstuffs] were identifiable as a danger to human health according to available scientific evidence at the time of the initial examination by the competent body, they would have to be subject to a risk assessment, and a finding of substantial equivalence would therefore be excluded.'[217] Since, harmful effects were not identified at the time of the initial examination,[218] the ECJ 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.

b) Legal Adoption of a Temporary Ban through a 'Safeguard Clause' under Article 12 of Regulation No 258/97

The second key issue relates to the circumstances under which a Member State could invoke the Precautionary Principle to activate a preventive action through a 'safeguard clause' within the context of a product having been brought to market through a simplified procedure. 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 ECJ. The Court properly viewed the safeguard clause as a specific expression of the Precautionary Principle; however, the level of

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[215] Ibid I-8197 [75-9].
[216] Ibid I-8198 [80].
[217] Ibid I-8198 [81].
[218] Ibid I-8199 [84].

evidence it required to implement a precautionary approach was highly 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[219] 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.[220] 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.[221] The national government stressed that, as such, Article 12 should be read in light of the purpose of the Precautionary Principle. The Norwegian Government, once again corroborating the Italian position, pointed out that a Member State may legitimately submit the application under the procedure provided by Article 13 of the Regulation[222] when it had doubts about substantial equivalence.[223]

The ECJ first addressed the concerns of the national Court regarding the effect the use of the simplified procedure had on the power of Member States to adopt measures such as the Decree of August 4, 2000. The Court 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.[224] 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.[225]

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[219] *Recommendation on Novel Foods* [1997] OJ L 253/1.

[220] Opinion of Advocate General Alber, above n 148, I-8140 [96]; *Monsanto Italy* [2003] ECR I-8166, I-8114 [8].

[221] *Monsanto Italy* [2003] ECR I-8166, I-8141 [99].

[222] *Novel Foods Regulation* [1997] OJ L 43/1, art 13(3) states:

> The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission.(...).

[223] Moreover, as stated by the Advocate General at para. 101 of his opinions: 'Until the relevant determination under Article 13 has been made, the Member State may suspend marketing under Article 12, provided that the conditions for the use of that safeguard clause are satisfied.' Opinion of Advocate General Alber, above n 148, I-8141 [101].

[224] *Monsanto Italy* [2003] ECR I-8166, I-8205 [104].

[225] Ibid I-8205 [106].

The ECJ referred to several previous European judgments and the twofold aim of Regulation No 258/97: to protect public health while promoting a functioning common market in novel foods.[226] The ECJ 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;[227] secondly, specific evidence of a risk to human health or the environment needs to be provided;[228] 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;[229] 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.[230] 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 ECJ 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.[231]

Finally, despite the statement by the ECJ that 'the safeguard clause must be understood as giving specific expression to the Precautionary Principle',[232] a protective measure through the safeguard clause must nevertheless be grounded in the specific evidence provided by the competent national authority.[233]

3 *Court's Ruling*

In response to the first issue, the ECJ concluded that 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.[234] As a consequence of this consideration, use of the simplified procedure to place such foods on the market was

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[226] *Novel Foods Regulation* [1997] OJ L 43/1.
[227] *Monsanto Italy* [2003] ECR I-8166, I-8205 [106].
[228] Ibid I-8207 [113].
[229] Ibid I-8205 [107].
[230] Ibid I-8207 [114].
[231] Ibid I-8206 [108].
[232] Ibid I-8206 [110].
[233] Ibid I-8207 [113].
[234] Ibid I-8216 [140.1].

permitted.[235] The Court concluded by clarifying 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.[236]

With regard to the second issue, the ECJ 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.[237] 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.

4 *Analysis*

Monsanto Italy[238] has provided some early clues regarding the future direction of the ECJ in relation to its treatment of the Precautionary Principle in relation to GMOs based on how the Court had substantively handled the risk assessment phase of its deliberations. As a result of the Court's approach to evidence regarding risks during that phase, it can be argued that the ECJ effectively pre-empted any possibility for the Precautionary Principle to be triggered in support of a ban as requested by a Member State. This lends itself to the appearance of favouring 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 ECJ held that Regulation No 258/97 supports an interpretation according to which the concept of substantial equivalence: (i) does not preclude that new foodstuffs with specific features could be considered substantially equivalent to traditional ones;[239] and (ii) should be contextualized through the work of international scientific institutions.

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[235] Ibid.
[236] Ibid.
[237] Ibid [140.2].
[238] Ibid.
[239] *Monsanto Italy* [2003] ECR I-8166, I-8196 [73-4].

The overarching aims of Regulation 258/97 are: (i) to protect public health against the risks arising from GMOs;[240] and (ii) to ensure the function of the internal market in GM foods.[241] As argued by the ECJ, 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. [emphasis added][242]

The ECJ 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. [emphasis added][243]

It merits noting that merely establishing substantial equivalence does not constitute a full safety assessment, even though it represents a crucial step in the assessment process.[244] 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'.[245] In that respect, the proposition by the ECJ relating that foods deemed not to be substantially equivalent would still need to be subject to an assessment of potential risks is not controversial. What is of greater interest relates to the use of language by the Court in the above points.

The above interpretation by the ECJ 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 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

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[240] *Novel Foods Regulation* [1997] OJ L 43/1, Preamble para 2, art 3(1).
[241] Ibid Preamble para 1.
[242] Monsanto Italy [2003] ECR I-8166, I-8196 [74].
[243] Ibid I-8197 [77].
[244] Opinion of Advocate General Alber, above n 148, I-8125 [44].
[245] *Recommendation on Novel Foods* [1997] OJ L 253/1.

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.

A further indication about the Court's preference emerges from its reasoning to endorse the availability of a simplified procedure to place novel foodstuffs on the European market. The ECJ 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.'[246] 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.[247]

Further issue 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 ECJ 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.[248] 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. It is also relevant to note that the ECJ required that the safeguard measure must be invoked by national government in light of the Precautionary Principle only when it has carried out a risk assessment that is *as complete as possible*, which may lead to an unattainable standard considering the high level of uncertainty surrounding GMOs.

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 ECJ ruled that the national evidence did not reveal a *necessity* to implement safeguard measures in light of the Precautionary Principle, thereby setting the bar

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[246] *Monsanto Italy* [2003] ECR I-8166, I-8198 [80].
[247] Ibid I-8182 [21].
[248] Ibid I-8198 [81]

for proving risk closer to a standard of 'real' than 'hypothetical'.[249] This approach to domestic evidence of risk assessment collides with a further key statement issued by the ECJ, according to which 'the safeguard clause must be understood as giving specific expression to the precautionary principle'.[250] This strict approach to evidence adopted by the ECJ in the risk assessment phase effectively prevented the Member State from triggering the Precautionary Principle to uphold its safeguard measure to ban the GMO maize line.

5 *Conclusion*

The analysis in this section has concluded that the ECJ substantively handled 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, as explained in Chapter II.

The following analysis of the *Austrian case* will provide a further opportunity to improve understanding of how the Court's handling of the risk assessment stage can pre-empt a proper application of the Precautionary Principle in the risk management stage.

B. *Austrian Case 2007: The Precautionary Principle in Light of a Derogation from a Harmonized Measure*

1 *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, as explained in Chapter II, allows derogation from a harmonisation measure provided that the domestic provisions are based on 'new scientific evidence relating to the protection of the

[249] Fernandez, above n 8, 338.
[250] *Monsanto Italy* [2003] ECR I-8166, I-8206 [110].

environment or the working environment on grounds of a problem specific to that Member State'. In support of its ban, the Austrian Republic submitted the 'Müller Report'[251] to the Commission, which sought to demonstrate that a specific problem in the Land Oberösterreich had arisen following the adoption of Directive 2001/18/EC, which made it necessary to derogate from the harmonised measure.[252]

The 'Müller Report' argued that the level of environmental protection afforded by Directive 2001/18/EC was not acceptable due to the problems that had arisen in Austria subsequent to adoption of the Directive.[253] 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 Directive 2001/18/EC,[254] and was therefore regarded as unresolved.[255]

Before undertaking its assessment, the Commission requested the European Food Safety Authority (EFSA) to provide an opinion to determine whether the Müller Report actually provided new scientific evidence. On July 4, 2003, EFSA advised that 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.[256] 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.[257]

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[251] 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>.

[252] *Austrian case* [2007] ECR I-7185, I-7190 [8].

[253] *Austrian case* [2007] ECR I-7185, I-7201 [42].

[254] *Release of GMOs Directive* [2001] OJ L 106/1

[255] Ibid I-7195 [21].

[256] *Opinion of Advocate General Sharpston* (Joined cases C-439/05 P and C-454/05 P) [2007] ECR I-7144, I-7153 [24].

[257] At the hearing, the Land Oberösterreich also specified that the draft measure was prompted by the imminent expiry of an agreement between Member States according to which they had temporarily agreed to no longer to issue consent for GMOs. However, due to its general nature, this did not help to change the findings of the Commission. Ibid I-7159 [44].

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

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 ECJ. 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.'[258]

An analysis of this reasoning of the ECJ in relation to the third plea will shed further light on how the Court's handling 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.

2 *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 issues because, once again, a decision by the ECJ 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.[259]

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

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[258] *Austrian case* [2007] ECR I-7185, I-7195 [21].
[259] Opinion of Advocate General Sharpston, above n 256, I-7160 [51].

Müller Report, which it presented as new scientific evidence insofar as it had to come to light subsequent to the adoption of Directive 2001/18/EC,[260] 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.[261] In particular, it argued that the Commission should have carried out a complete scientific analysis of the risks, and fulfil its obligation to provide reasons for its decision.[262] The appellants also contested the CFI finding of an absence of a specific problem for the purpose of satisfying Article 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. They argued that the judgment was 'inconsistent with the obligation to take as a basis a high level of protection when adopting health, safety, environmental and consumer protection measures on the basis of Article 95(5) of the *EC Treaty*.'[263] On a more focused point, the applicants contended that the term 'specific' provided by that Article should not be considered synonymous with 'unique'.[264] They also argued that the Article referred to 'particular problems', but not 'exclusive problems' of a Member State.[265] This interpretations led the CFI to not examine the other conditions provided by Article 95(5) of the *EC Treaty*, infringing Community Law as a result.[266] 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.[267]

In its response, the Commission stressed that the general considerations of appellants were unable to invalidate the more concrete evaluations carried out by EFSA.[268] It underscored that *new scientific evidence* and *protection of the environment* could be not

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[260] *Release of GMOs Directive* [2001] OJ L 106/1.
[261] *Austrian case* [2007] ECR I-7185, I-7202 [47].
[262] Ibid I-7202 [47].
[263] Ibid I-7202 [48].
[264] Ibid I-7204 [54].
[265] Ibid.
[266] Ibid.
[267] Ibid I-7203 [49].
[268] Opinion of Advocate General Sharpston, above n 256, I-7161 [55].

considered elements of *a specific problem*, 'but that all three are cumulative conditions for the application of art. 95(5) EC';[269] consequently, if even even one condition has not been satisfied, then the request has to be rejected.[270] With regard to the Precautionary Principle, the Commission merely corroborated the explanation provided by the CFI in rejecting the plea concerning its infringement.[271] 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 stressed the absence of an obligation by the CFI to examine in detail the conditions concerning the existence of a specific problem.[272] It concluded, therefore, 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.'[273]

The ECJ emphasised the 'close link' between legal adoption of national measures by a Member State pursuant to Article 95(5) of the EC Treaty and the assessment of the scientific evidence put forward by the Member State.[274]According to the Court, Article 95(5) requires that the introduction of a domestic provision derogating from a harmonisation measure – in this case, provisions of Directive 2001/18/EC[275] - 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.[276]

The ECJ 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.[277] 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 of those conditions.[278] Consequently, the

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[269] Ibid I-7162 [56].
[270] Ibid.
[271] *Austrian case* [2007] ECR I-7185, I-7203 [52].
[272] Ibid I-7204 [55].
[273] Ibid.
[274] Ibid I-7204 [56].
[275] *Release of GMOs Directive* [2001] OJ L 106/1.
[276] Ibid I-7205 [57]. Finally, the proposed provision must provide also the grounds for introducing it. To this regard, the ECJ pointed out that the proposed provision and the grounds at the basis of it must be notified to the Commission.
[277] Ibid I-7206 [66].
[278] Ibid I-7207 [68]-[70].

CFI had not infringed Article 95(5) of the *EC Treaty*.[279]

3 *Court's Ruling*

The ECJ 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.[280]

4 *Analysis*

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', however, Austria attempted to argue the Precautionary Principle by invoking Article 95(5) of the *EC Treaty* to uphold its 'derogation of a harmonisation measure' that was contained within Directive 2001/18/EC.[281] Despite the different approaches, this case raises similar concerns about the Court's handling of evidence during 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,*[282] 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 pat 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'.[283] 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 where the Precautionary Principle is applied

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[279] Ibid I-7208 [72].
[280] Ibid I-7207 [71], I-7208 [74].
[281] *Release of GMOs Directive* [2001] OJ L 106/1.
[282] *Monsanto Italy* [2003] ECR I-8166.
[283] *EC Treaty,* art 95(5).

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. This conflicts with EU policy on the Precautionary Principle to ensure a high level of protection for the environment set out by COMM(2000).[284] By dismissing the 'Müller Report', the ECJ 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 invites concern about limitations on the discretionary power to Member States to implement a precautionary approach.[285]

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 (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 an overly restrictive or narrow approach to evidence during the risk assessment phase, especially in an indefinite field such as the genetic engineering where 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 ECJ failed in their duty to provide adequate reasoning by virtue of not having examined all of the evidence in light of the Precautionary Principle.[286] 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:

> In English…'[e]vidence' normally designates the raw material from which conclusions may be drawn. The picture is less clear however when one looks at a broader range of language versions of Article 95(5) EC. The Dutch ('nieuwe wetenschappelijke gegevens') appears to agree with the English. Several of the Latin languages use terms ('preuves scientifiques nouvelles' in French, 'nuove prove scientifiche' in Italian and 'novas provas cientificas' in Portuguese) which may have a broader meaning. And the Spanish ('novedades científicas') and German ('neue wissenschaftliche Erkenntnisse') versions certainly appear more

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[284] *COMM(2000)*, above n 18.
[285] Floor M. Fleurke, 'Analysis - What Use for Article 95(5) EC? - An Analysis of Land Oberosterreich and Republic of Austria v Commission' (2008) 20(2) *Journal of Environmental Law* 267, 273.
[286] Opinion of Advocate General Sharpston, above n 256, I-7160 [51].

> capable than the English of bearing the meaning for which the appellants argued at first instance.[287]

This would suggest that what the ECJ considers 'new scientific evidence' is open to interpretation. As the ECJ chose to apply a narrow approach in the *Austrian case*,[288] it effectively prioritised one policy aim (to promote a common market) over the national interest (to provide a higher standard of health or environmental protection than the EU) as a direct result of its decision-making during the risk assessment stage.

Although it was not reported by the ECJ in its judgment, the Commission had submitted two proposals to the Environment Council in relation to the maize line in question.[289] 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'.[290] For this reason, the Commission was invited:

> to gather further evidence on the GMO in question and further assess whether the measure taken by [Austria] aimed at suspending as a temporary precautionary measure [its] placing on the market [is] justified and, whether the authorisation of such [an] organism still meets the safety requirements of Directive 2001/18/EC.[291]

Thus, through its first declaration, the Council justified dismissal of the 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 Commission again consulted the EFSA, requesting that it 'take account of any further scientific information that had arisen subsequent to the previous scientific opinion concerning the safety of this GMO.'[292] Once it

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[287] Ibid I-7178 [124].
[288] *Austrian case* [2007] ECR I-7185.
[289] In particular, relying on the opinion of EFSA provided on 8 July 2004, the Commission submitted on 29 November 2004 a draft Decision requesting Austria to repeal its provisional safeguard measure, for consideration by the Committee established under Article 30 of Directive 2001/18/EC. However, since the Committee did not deliver an opinion, the Commission submitted to the Council a proposal recommending what measures should to be taken. *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.
[290] Ibid 6-7(13).
[291] Ibid.
[292] Ibid 7(14).

received a new opinion from EFSA,[293] the Commission submitted a new proposal to the Council to require repeal of the Austrian safeguard measure.[294]

On December 18, 2006, the Environment Council, with qualified majority, re-stated its opposition to the Commission's proposal.[295] Through its second decision, the Council indicated 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.'[296] This second denial by the Council highlights the importance of carrying out a systematic risk assessment to address national concerns, and underscores the problem raised by a high level of uncertainty in the assessment of GMOs and corresponding need for greater rigour in the risk assessment stage.[297]

5 *Conclusion*

This second case sheds further light on how the ECJ substantially handled evidence during the risk assessment phase, and its corresponding impact on the application of the Precautionary Principle. As in the *Monsanto Italy,*[298] 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 ECJ during the risk assessment stage. The analysis of the third case will provide further support for this observation, however in the context of an attempt to invoke the Precautionary Principle through both a 'safeguard clause' and 'emergency measure'.

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[293] The EFSA had concluded its first opinion on 8 July 2004.
[294] Proposal for a Council Decision, above n 289, 7(16).
[295] Ibid 7(17).
[296] Ibid 7(18). Since the Council had not reached a qualified majority for the approval or the rejection of the proposal, the Commission adopted its proposal according to the its procedure. The consequent declaration of the Council invited Austria to 'take the necessary steps to terminate the prohibition of import and processing into food and feed products of Zea mays L. line MON810'. Ibid 8(24).
[297] Ibid 7(18).
[298] *Monsanto Italy* [2003] ECR I-8166.

C. *Monsanto France 2011: The Precautionary Principle in Light of an Emergency Measure along with a Safeguard Clause*

1 *Background to the Dispute*

In 1995, relying on Directive 90/220/EEC,[299] which was subsequently replaced by Directive 2001/18/EC,[300] the multinational company Monsanto 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.[301] 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.[302]

In 2004, Monsanto duly notified the Commission of MON 810 maize as an 'existing product' under the new Regulation 1829/2003.[303] On May 4, 2007, before the expiry of its permission to trade, Monsanto applied for renewal of its authorisation to place the MON 810 maize on the market under the same Regulation 1829/2003,[304] rather than through Directive 2001/18/CE[305] which as mentioned had replaced Directive 90/220/EEC under which the product had been initially approved in 1998.[306]

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[299] *Release of GMOs Directive* [1990] OJ L 117/1.
[300] *Release of GMOs Directive* [2001] OJ L 106/1.
[301] The product was (and it is still) subject to the provisions of *GMO Regulation* [2003] OJ L 268/1.
[302] Over the following decade, MON810 has been, in fact, cultivated in several European countries. Patricia B. Robbins, 'GMO Reignited in Science but Not in Law: A Flawed Framework Fuels France's Stalemate' (2014) 69(3) *Food and Drug Law Journal* 429, 431.
[303] *GMO Regulation* [2003] OJ L 268/1, art 20(1a), which states:
> in the case of products which have been authorised under Directives 90/220/EEC or 2001/18/EC, including use as feed, under Directive 82/471/EEC, which are produced from GMOs, or under Directive 70/524/EEC, which contain, consist of or are produced from GMOs, operators responsible for placing on the market the products concerned shall, within six months after the date of application of this Regulation, notify the Commission of the date on which they were first placed on the market in the Community.

[304] *GMO Regulation* [2003] OJ L 268/1, art. 20(4), which states:
> Within nine years from the date on which the products referred to in paragraph 1(a) were first placed on the market, but in no case earlier than three years after the date of application of this Regulation, operators responsible for placing them on the market shall submit an application in accordance with Article 23, which shall apply *mutatis mutandis*.

[305] *Release of GMOs Directive* [2001] OJ L 106/1, 1.
[306] *Release of GMOs Directive* [1990] OJ L 117/1.

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, by on Order made in February 2008, prohibited the planting of maize seed varieties derived from maize MON 810 until a decision on the renewal of the authorisation had been taken.[307] The French Minister notified the Commission of its action, classifying it first as an 'emergency measure' in accordance with Article 34 of Regulation No 1829/2003[308] and Articles 53 and 54 of Regulation No 178/2002,[309] and then also as a 'safeguard clause' pursuant to Article 23 Directive 2001/18.[310] The 'emergency measure' enables a Member State to take action where products are 'likely to constitute a serious risk to human health, animal health or the environment'.[311]

In the face of this national ban, Monsanto and other companies (hereinafter 'Monsanto and others') brought an action in February 2008 for an annulment of the French order before the Conseil d'État,[312] which decided to stay the proceeding for annulment of the French order and refer the matter to the ECJ for a preliminary ruling.[313]

The ECJ addressed three issues: (i) 'which legal scheme must be applied to a product already authorised on the basis of Directive 90/220/EEC, and then notified as an existing product in accordance with Regulation No 1829/2003/EC, on the basis of which the renewal of authorisation was then applied for';[314] (ii) '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';[315] and, (iii) 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 Directive 2001/18/EC and Article 34 of the Regulation 1829/2003.[316]

The first question raises interesting procedural issues, however it is the latter two

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[307] 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.
[308] *GMO Regulation* [2003] OJ L 268/1, art 34.
[309] *Food Law Regulation* [2002] OJ L 244/1, arts 53-4.
[310] *Release of GMOs Directive* [2001] OJ L 106/1, art 23. Thus, the French Government did not rely solely on a 'safeguard clause' as the Italian Republic in *Monsanto Italy* [2003] ECR I-8166.
[311] *GMO Regulation* [2003] OJ L 268/1, art. 34.
[312] The Conseil d'État is the highest French administrative authority. It is the final arbiter of cases relating to executive power, local authorities, independent public authorities, public administration agencies or any other agency invested with public authority.
[313] *France Monsanto* [2011] ECR I-00000.
[314] *Opinion of Advocate General Mengozzi*, (Joined Cases C-58/10 to C-68/10) [2011] ECR 00000, (26).
[315] Ibid 14.
[316] *France Monsanto* [2011] ECR I-00000 [38].

questions that provide relevant insights into the Court's handling of the risk assessment phase as pre-cursor to invoking the Precautionary Principle. Indeed, as will be explained in the analysis of this case and Chapter IV, this judgement 'could have significant legal-political and practical consequences for EU multi-level governance of GMOs'.[317]

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

a) Legal Adoption of Unilateral Measures by Member States

The national Court aimed to examine whether a Member State could adopt unilateral measures other than as referred to in Article 34 of Regulation No 1829/2003,[318] as had been done by the French Government in this case.[319] The reasoning of the Court on this issue, however, appears to be inconsistent. Despite the adoption of a rigid literal interpretation of the provisions of the Regulation, the Court claimed it needed to interpret those provisions in light of the Precautionary Principle. However, a literary interpretation of procedural conditions would seem to collide with the prospect of effectively applying a precautionary approach by a Member State.

Monsanto and others, supported by the Commission, based their arguments on a systematic reading of Article 34 of Regulation No 1829/2003[320] which, in order to adopt emergency measures, refers to the procedure set out in Articles 53 and 54 of Regulation No 178/2002.[321] 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.[322] A national government could take unilateral measures only in a case where the Commission fails to act, as set out in the Regulation.[323]

In contrast, the French Government suggested a different interpretation of Article 53. It was argued that, according to art. 53, the Commission has to adopt appropriate measures where the problem 'cannot be contained satisfactorily by means of measures taken by the

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[317] 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' (2012) 3(3) *European Journal of Risk Regulation* 445, 449.
[318] *GMO Regulation* [2003] OJ L 268/1, art 34.
[319] Opinion of Advocate General P. Mengozzi, above n 314, para 46.
[320] *GMO Regulation* [2003] OJ L 268/1, art 34.
[321] *Food Law Regulation* [2002] OJ L 244/1, arts 53-4.
[322] *France Monsanto* [2011] ECR I-00000 [30-2].
[323] Opinion of Advocate General P. Mengozzi, above n 314, para 47.

Member State(s) concerned'.[324] 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.[325] Hence, the national perspective is diametrically opposed to the reading supported by Monsanto and others along with the Commission.

The ECJ reflected on the wording of Article 34 of Regulation No 1829/2003. It formed the view that Article 34 'does not make the adoption of emergency measures subject to the substantive conditions provided for in Article 53 of Regulation No 178/2002.'[326] If a Member State intends to adopt emergency measures pursuant to Article 34 of Regulation No 1829/2003, 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.[327] 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 to Article 53, can the Member State adopt an interim protective (after which it must immediately inform the Commission and other Member States).[328]

On this point, the ECJ made explicit reference to its decision in *Monsanto Italy,*[329] referring to the finding that procedural conditions provided by Article 54 have to be interpreted:

> not only in the light of the wording of that provision, but also in the light of the purpose of Regulation No 1829/2003 and 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.[330]

Therefore, the ECJ concluded that a Member State is authorized to adopt emergency measures pursuant to Article 34 Regulation No 1829/2003/EC, 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.[331]

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[324] *Food Law Regulation* [2002] OJ L 244/1, art 53(1).
[325] Opinion of Advocate General P. Mengozzi, above n 314, para 49.
[326] *France Monsanto* [2011] ECR I-00000 [67].
[327] Ibid [69].
[328] Ibid [70].
[329] *Monsanto Italy* [2003] ECR I-8166, I-8206 [110].
[330] *France Monsanto* [2011] ECR I-00000 [71].
[331] Ibid [74].

b) Conditions for the Adoption of Emergency Measures in Light of the Precautionary Principle

This issues relates to understanding of the nature of requirements imposed by Article 23 of Directive 2001/18/EC[332] and Article 34 of Regulation No 1829/2003/EC.[333] 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.

This question arose from doubts expressed by the national Court regarding the different formulation of these two Articles which, even if both were finalized to allow the domestic adoption of protective measures, require different conditions to implement under a precautionary approach. By interpreting the wording of Article 34 of Regulation 1829/2003/EC concisely, the ECJ 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.[334] Moreover, it added that the presence of a risk must be established by reference to new evidence based on reliable scientific data.[335] With regard to the degree of risk, the Court, again by explicit reference to the *Monsanto Italy,*[336] declared that measures pursuant to Article 34 Regulation 1829/2003 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.'[337]

The ECJ also reiterated a procedural aspect of European law. 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 the substantive conditions laid down by Article 34 Regulation 1829/2003 and procedural considerations set out under Article 54 Regulation No 178/2002.[338] It is the duty of the ECJ to ensure the uniformity of European Union law, but

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[332] *Release of GMOs Directive* [2001] OJ L 106/1, art 23.
[333] *GMO Regulation* [2003] OJ L 268/1, art 34.
[334] *France Monsanto* [2011] ECR I-00000 [75].
[335] Ibid [76].
[336] *Monsanto Italy* [2003] ECR I-8166, I-8205 [106-7].
[337] *France Monsanto* [2011] ECR I-00000 [77].
[338] Ibid [79]. The ECJ highlighted, in fact, that in order to avoid artificial disparities in the treatment of a serious risk, 'the assessment and management of a serious and evident risk ultimately come under the sole responsibility of the Commission and the Council, subject to review by the European Union Courts.' Ibid [78].

only after the matter had been addressed by a national Court.[339] 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'.[340]

The ECJ concluded by reiterating that, in addition to *urgency*, Article 34 Regulation 1829/2003/EC requires the Member States to establish the existence of situation that is likely to constitute a *clear and serious risk* to human health, animal health or the environment.[341]

It should be noted that, in the course of analysing this question, no reference was made by the ECJ 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 Directive 2001/18/EC and Article 34 Regulation 1829/2003/EC.

3 *Court's Ruling*

With regard to the questions reviewed in this section,[342] the ECJ held that Member States could adopt emergency measures under Article 34 of Regulation 1829/2003 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.'[343]

4 *Analysis*

France Monsanto[344] 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

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[339] Ibid.
[340] Ibid [80].
[341] Ibid [81].
[342] With regard to the first question, the ECJ held that Member States cannot provisionally suspend or prohibit their use or sale according to Article 23 of Directive 2001/18/EC. However, they can adopt such measures pursuant to Article 34 of Regulation No 1829/2003.
[343] *France Monsanto* [2011] ECR I-00000 [77].
[344] *France Monsanto* [2011] ECR I-00000.

(Directive 90/220/EEC),[345] and then notified to the Commission as an 'existing product' under a newer Regulation.[346] 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 the more stringent provisions of Directive 2001/18/EC[347] (which had replaced Directive 90/220). 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 Preamble of Directive 2001/18/EC, GMOs 'which have conventionally been used in a number of applications and have a long safety record' are to be excluded from reassessment.[348] 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.[349]

This outcome, however, stands in contrast to the more strict approach imposed by the Court on Member States to invoke an emergency measure under Article 34 of Regulation 1829/2003 only after providing a risk assessment that is as 'complete as possible' and only when 'necessary'. It should be recalled that the insistence on risk assessment being 'as complete as possible' was also a controversial outcome in *Monsanto Italy*.[350] The flow-on effect of the Court's reasoning, therefore, is that the evidentiary burden on the French Government to restrict the product was significantly higher than that originally faced by Monsanto.

A further similarity in approach to evidence emerges when this case is considered against *Monsanto Italy* discussed earlier in this Chapter.[351] In *Monsanto Italy,* the ECJ permitted access to a simplified procedure to market novel foods derived from GMOs which contained transgenic proteins, despite the agreement between Member States and the

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[345] *Release of GMOs Directive* [1990] OJ L 117/1.
[346] Indeed, a novel food can be notified as 'existing product' according to the conditions set out in *GMO Regulation* [2003] OJ L 268/1, art 20.
[347] *Release of GMOs Directive* [2001] OJ L 106/1.
[348] Ibid.
[349] Robbins, above n 302, 436.
[350] *Monsanto Italy* [2003] ECR I-8166.
[351] *Monsanto Italy* [2003] ECR I-8166.

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 Regulation 1829/2003/EC 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 Chapter, 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.[352] According to the interpretation of the ECJ, Article 34 Regulation No 1829/2003/EC 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.[353] Moreover, a measure must rely on *new evidence based on reliable scientific data*.[354] Advocate General Mengozzi offered an alternative reading of the provision which would be more favourable to a precautionary approach, suggesting that:

> for the adoption of emergency measures, there must (a) clearly be a risk that harm will be caused, and (b) a significant probability that the harm in question will occur, even though it has not necessarily been determined precisely (the 'serious' nature of the risk interpreted in the light of the precautionary principle).[355]

As a final point of reflection on this case, it merits recalling that the ECJ also failed to provide detailed reasoning in the *Austrian case* in relation to the issue of new scientific evidence, which has been described as a failure by the Court to discharge its duty with regard to proper expression of the Precautionary Principle.[356] In *France Monsanto,* the Court failed to carry out an adequate reading of the conditions under which protective measures set out by Article 23 of Directive 2001/18/EC and Article 34 of Regulation 1829/2003 could be invoked in relation to the Precautionary Principle, nor did it address the third question put forward by

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[352] *France Monsanto* [2011] ECR I-00000 [71].
[353] Opinion of Advocate General P. Mengozzi, above n 314, at paras 66-7.
[354] *France Monsanto* [2011] ECR I-00000 [76].
[355] Opinion of Advocate General P. Mengozzi, above n 314, para 68.
[356] Opinion of Advocate General Sharpston, above n 256, I-7160 [51].

the National Court.[357] This lack of elaboration of the questions that would serve to provide guidance on protective measures arguably reflects a superficial stance towards the interests of Member States to implement a precautionary approach in the field of GMOs.

5 *Conclusion*

The manner in which the risk assessment stage was handled by the ECJ in this case was met by strong objections by the French Government, which expressly declared its disagreement with the final European appraisals. For this reason, notwithstanding the deliberation of the ECJ 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',[358] extending the prohibition of MON 810 cultivation.[359] 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'[360] because it contains new and important scientific data concerning risks to the environment not previously examined by EFSA's GMO Panel.[361] Even so, 'the GMO Panel again found no new scientific evidence to support an emergency measure regarding MON 810'.[362] Consequently, on August 1, 2013, the Conseil d'Etat again declared the French ban to be illegal.[363] To this point, despite the cancellation by the French Council of State of the ban on growing this GM maize, a few days later, the

[357] A detailed comparison between the conditions laid down by Article 23 Directive 2001/18/EC and Article 34 Regulation 1829/2009/EC is provided by Advocate General Mengozzi in his opinion on the case. Opinion of Advocate General P. Mengozzi, above n 314, paras 57-71.

[358] Marcel Kuntz, John Davison and 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' (2013) 31(6) *Nature Biotechnology* 498.

[359] Marcel Kuntz, John Davison and Agnès E Ricroch, 'What the French Ban of Bt MON810 Maize Means for Science-Based Risk Assessment' (2013) 31(6) *Nature Biotechnology* 49, 498.

[360] Robbins, above n 302, 432.

[361] In particular, the failure by the ECJ to consider new scientific data provided by the French Government (despite that it existed at the time of the judgment) provides another basis for criticism of the risk assessment process carried out at the European level. See Kuntz et al, above n 346, 498. It also merits noting that the interim protective measures were adopted by France after the ruling pursuant to art. 54(3) of Regulation No 178/2002. See Enrica Blasi, 'I nuovi margini del potere decisionale degli stati europei in materia di organismi geneticamente modificati' (2015)1 *Rivista quadrimestrale di diritto dell'ambiente* 150, 157. The judgment by the ECJ demonstrated that the emergency measures under art. 34 of Regulation 1829/2003 can be legally adopted only in accordance with the procedural conditions set out in Article 54 of Regulation (EC) No 178/2002.

[362] Robbins, above n 302, 433. Thus, even if adopted according to the procedural conditions set out in Article 54 of Regulation (EC) No 178/2002, the emergency measure adopted by French Government after the ruling of the ECJ was, again, considered not scientifically supported by new evidence.

[363] Ibid.

French President François Hollande confirmed an extension of the moratorium on the cultivation of Monsanto's GM maize MON 810.[364]

The continued reluctance of Member States to GMOs, including France's reaction during and after the ECJ decision, contributed a decision by the European Commission in 2013 'to freeze the approval process for genetically modified food crops through the end of its mandate next year.' The Commission continued to work on an agreement with Member States.[365] After several years, as explained in Chapter II, Directive 2015/412 introduced Article 26-b into European Directive 2001/18/EC enabling Member States 'to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory'.[366]

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[364] 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>. Immediately after the announcement of the French Council of State to annulment of previous ban on the cultivation of GM maize MON 810, the Ministers of Agriculture and Ecology, Stéphane Le Foll and Philippe Martin stressed 'the government's commitment (to) maintain the moratorium on the cultivation of GMO seeds.': at 2.

[365] EU freezes approval of GM crops to 2014, Phys. Org (January 22, 2013), 1 < http://phys.org/news/2013-01-eu-gm-crops.html>; European Commission, 'GMO legislation', http://ec.europa.eu/food/plant/gmo/legislation/index_en.htm.

[366] *Cultivation of GMOs Directive* [2001] OJ L 68/1.

CHAPTER IV – A HIGH LEVEL OF PROTECTION FOR HEALTH AND THE ENVIRONMENT VS FREE CIRCULATION OF GMOS ON THE EUROPEAN MARKET: INTERESTS IN CONFLICT

This thesis examined how the ECJ substantively handled the risk assessment phase in three seminal cases between 2003-2011 where Member States had sought to trigger the Precautionary Principle in order to sustain bans on GMOs within their respective territories: *Monsanto Italy,*[367] *Austrian case*[368] and *France Monsanto.*[369] The purpose of this analysis, as stated in the Introduction to this thesis, was to elucidate aspects of the nature and parameters of the current law governing the regulation of GMOs in the EU in order to identify shortcomings, recommend improvements and delineate areas for further research. The analysis was carried out against the backdrop of a succinct review of the conceptual foundations of the Precautionary Principle in Chapter I, which provided a broad classification of 'weak' and 'strong' approaches to the principle based on the degree to which it is used to promote the aims of environmental or health protection. Chapter I also set out the significance of 'risk' and the role of 'risk assessment' as the critical stage of 'risk governance' or, as it is referred to in the European policy framework, 'risk analysis', for the purpose of focusing the analysis of the ECJ cases. Chapter II set out the European legal framework for the Precautionary Principle and the regulation of GMOs, and explained the three mechanisms that were employed by Member States in the analysed cases to invoke the Precautionary Principle in their bids to uphold bans placed on GMOs within their respective territories: safeguard clauses, derogation of a harmonisation measure, and emergency measures. Chapter III provided some preliminary conclusions emerging from the analysis of each case, and sheds light on various shortcomings of the European legal framework to regulate GMOs. More specifically, the analysis in Chapter III demonstrated the impact of the Court's handling of evidence during the risk assessment stage on the ability of Member States to successfully trigger the Precautionary Principle to support their precautionary measures. Chapter IV will now present key findings that emerge from an analysis across the three seminal judgments by the ECJ and preceding Chapters. This concluding Chapter will also provide some critical reflections on the significance of these findings for understanding the

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[367] *Monsanto Italy* [2003] ECR I-8166.
[368] *Austrian case* [2007] ECR I-7185.
[369] *France Monsanto* [2011] ECR I-00000.

Precautionary Principle as applied to the regulation of GMOs, including possible directions for further research.

A. *Key Findings from the Analysis of how the ECJ Handled the Risk Assessment Stage Across Three Seminal Judgements (2003-2011)*

Italy, Austria and France were each unsuccessful in their attempts to secure the approval from the ECJ for precautionary measures to ban GMOs within their territories for the purpose of health and environmental protection. This was despite having employed different legal avenues to invoke the Precautionary Principle: Italy had employed a 'safeguard clause' set out under Article 12 of Regulation 258/97;[370] Austria and Land Oberösterreich had attempted a derogation from a harmonisation measure under the process established by Article 95(5) of the *EC Treaty*; and France triggered both a 'safeguard clause' under Article 23 of Directive 2001/18/EC[371] and 'emergency measure' pursuant to Article 34 of Regulation 1829/2003/EC.[372] The doctrinal analysis of these complex cases in Chapter III leads to a number of critical insights. These can be reduced to three key findings for the purpose of responding to the research question, which is to determine how the ECJ substantively handled the risk assessment phase in the above cases. The first two emerge directly as principles that guide decision-making by the ECJ during the risk assessment stage, which is where the Court evaluates the nature and quality of evidence provided by Member States to justify precautionary measures to ban a GMO. The third finding relates to the implications the Court's application of those principles to exclude evidence from its consideration during the risk management stage where the precautionary principle is applied under the European framework.

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 principle was clearly established in *Monsanto Italy*[373] 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

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[370] *Novel Foods Regulation* [1997] OJ L 43/1, art 12.
[371] *Release of GMOs Directive* [2001] OJ L 106/1, art 23.
[372] *GMO Regulation* [2003] OJ L 268/1, art 34.
[373] *Monsanto Italy* [2003] ECR I-8166.

by the Court.[374] The principle was also sustained in *France Monsanto,*[375] which held that the 'emergency measure' under Article 34 of Regulation 1829/203/EC must rely on 'new evidence based on reliable scientific data.'

The second key finding relates to the requirement that the evidence relied upon by Member States to justify a precautionary measure must arise from risk assessment that has been carried out in a manner that is 'as complete as possible'. Although the issue was not dealt with explicitly in the *Austrian case*,[376] the principle can nevertheless be inferred from the Court's insistence on the provision of 'new' evidence as part of a Member State's risk assessment. The principle was, however, clearly established in *Monsanto Italy,*[377] which was later affirmed by the ECJ in *France Monsanto.*[378] This represents a strong endorsement of the principle across the timeline of cases, including the most recent substantive judgment on the issue.

The third key finding emerges from the observed impact of the ECJ's application of the above two principles to exclude evidence relating to risks associated with GMOs provided by Member States to justify precautionary measures to ban GMOs within their territories. This finding is in the form of an observation that the ECJ'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. As explained in Chapter II, COMM(2000) provided common guidelines for a wide scope of application of the Precautionary Principle, including where an objective scientific process did not allow for a sufficiently reliable determination of risk.[379] In each of the three judgements analysed in Chapter III, the ECJ ruled that evidence crucial to the case of Member States was to be excluded on the basis of failing to provide new scientific evidence and/or not having arisen from a process of risk assessment that was 'as complete as possible'. The consequence of excluding crucial evidence in each case was effectively to pre-empt the outcome of the consideration of the Precautionary Principle in the risk management phase in favour of the commercial litigants. As no valid evidence, according to the ECJ, had been provided by the Member States to support their positions, their actions to take precautionary measures to ban GMOs were held to be invalid.

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[374] *Austrian case* [2007] ECR I-7185, I-7204 [56].
[375] *France Monsanto* [2011] ECR I-00000 [76].
[376] *Austrian case* [2007] ECR I-7185.
[377] *Monsanto Italy* [2003] ECR I-8166.
[378] *France Monsanto* [2011] ECR I-00000.
[379] *COMM(2000)*, above n 18.

B. *Implications for Understanding the Precautionary Principle and Regulation of GMOs in Europe and Directions for Further Research*

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. However, the question moving forwards, building on the research question, relates instead to the implications arising from the principles or trends emerging from those decisions.

It merits reiterating that the Member States failed to gain the support of the ECJ in all three 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. Thus, it can be argued that the efforts by Member States to protect health or the environment within their territories were unsuccessful against the competing priority to promote a common market under EU policy.[380]

The analysis in this thesis therefore suggests a disconnect between the outcomes of the three cases, which are a direct result of the decision-making applied by the Court during the risk assessment phase, and broader policy framework of the EU and objections of Member States.

Firstly, the trio of cases suggests that the ECJ has favoured a 'weak' expression of the Precautionary Principle insofar as it has effectively placed a higher onus on Member States to provide evidence in support of their ban of GMOs than on commercial litigants, thereby favouring trade liberalisation. This result is in contrast to the 'strong' application of the Precautionary Principle reflected in the EU framework, which should arguably have encouraged the Court to take a less narrow approach to evidence regarding risks. As anticipated in Chapter I, the analysis of these cases sheds important light on understanding how the Precautionary Principle is translated through judicial decision-making when considered in the light of an overarching policy framework. It invites further reflection on how the Precautionary Principle can be better expressed through more detailed guidance in official policies to assist decision-makers, which was foreshadowed as an area of concern in Chapter I.

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[380] COMM(2000), above n 18.

The second disconnect evident from the ECJ cases also relates to the policy arena. As explained in Chapter II, EU policy aims to promote the highest standard of health and environmental protection. A logical extension of this policy aim would be to prioritise health and the environment over commercial concerns. This consideration is linked to the manner in which the Precautionary Principle is expressed as a mechanism to navigate risks. As such, as anticipated in Chapter II, the analysis in this thesis reinforces concerns about the lack of sufficient policy guidance in relation to application of the Precautionary Principle, particularly with regard to GMOs.

The third implication arising from this study points to a broader political question relating to the role and function of the ECJ as an institution of the EU. As explained in Chapter II, the EU is faced with a challenging environment owing to the division of competences between the EU and Member States under the *Treaty of Lisbon*. Common commercial policy is an exclusive competence of the EU, whereas health protection is a supporting competence and environmental protection is a shared competence. The outcome of the three cases analysed in this thesis supports a perception of the dominance of interests promoting a common market, which in all fairness are validly an exclusive jurisdiction of the EU. As demonstrated by the French response following the decision by the ECJ in *France Monsanto*,[381] however, Member States are prepared to go to extreme lengths to advance their national policy objectives when they relate to health and the environment within their territory. This arguably reflects a deeper rift between Member States and the EU in which the ECJ, as an institution of the EU, plays an important role.

As a final point, the analysis of the ECJ's handling of the risk assessment stage in the three cases suggests a further disconnect between the Court's understanding of the nature of scientific evidence (and expectation of Member States to provide it) and the limitations of science to predict risks in the field of GMOs. As explained in Chapter III, concerns about the Court's handling of evidence in the three cases reinforces those expressed in Chapter I regarding the nature of risk in the application of the Precautionary Principle. Taken together, the implications of findings from this thesis 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 the law to navigate the complex issues raised by the science of GMOs.

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[381] *France Monsanto* [2011] ECR I-00000.

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