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Precautionary Principle: Does It Play a Role in EU Decision-making?

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To Omkar, who met me at the beginning of this journey and went on it with me through all its twists and turns, keeping me grounded and on track.

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TABLE OF ABBREVIATIONS

ANSES	French National Food Safety Agency [Agence Nationale Sécurité Sanitaire Alimentaire Nationale]
BFR	German Federal Institute for Risk Assessment [Bundesinstitut für Risikobewertung]
BVL	Federal Office of Consumer Protection and Food Safety[Bundesamt für Verbraucherschutz und Lebensmittelsicherheit]
CBA	Cost Benefit Analysis
CJEU	Court of Justice of the European Union
COPA-COGECA	Committee of Professional Agricultural Organizations-General Confederation of Agricultural Cooperatives [Comité des organisations professionnelles agricoles-Comité général de la coopération agricole de l'Union européenne]
Ctgb	Board for the Authorisation of Plant Protection Products and Biocides [College voor de toelating van gewasbeschermingsmiddelen en biociden]
DEPHY	Network for demonstration, trial and reference production for plant protection product use systems [Réseau de démonstration, expérimentation et production de références sur les systems]
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EI	Independent Evaluating Authorities
EPRS	European Parliamentary Research Service
EU	European Union
GLP	Good Laboratory Practices
GM	Genetically Modified
GT	Glyphosate Tolerant
IARC	International Agency for Research on Cancer
IPM	Integrated Pest Management
LPT	Laboratory of Pharmacology and Toxicology
MRL	Maximum Residue Level
NGO	Non-governmental Organization
PAFF	Standing Committee on Plants, Animals, Food and Feed
PAN	Pesticide Action Network
PBT	persistent, bio-accumulative, and toxic
PDI	Public Declaration of Interest
PoP	Persistent organic Pollutant
PP	Precautionary Principle
PPP	Plant Protection Product
PPR	Panel on Plant Protection Products and their Residues
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RECIPES	REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders

SKL	Foundation for Quality Control of Agricultural Equipment [Stichting Kwaliteitseisen Landbouwtechniek]
SPRINT project	Sustainable Plant Protection Transition project
TFEU	Treaty on the Functioning of the European Union
vPvB	very Persistent very Bio-accumulative
Wgb	Plant protection products and biocidal products Act [Wet gewasbeschermingsmiddelen en biociden]
WHO	World Health Organization

LIST OF TABLES, FIGURES AND GRAPHS

Chapter 1: Introduction

'Better safe than sorry' is an oft-repeated adage, appearing in different languages and cultures indicating that the idea of precaution is not new. Such a precautionary attitude seems to stem from the interplay between the basic human instincts of the constant pursuit of new knowledge and the fear of the unknown. The need to maintain a balance between innovation and uncertain externalities is most acute in relation to threats to the environment and human life, given the magnitude and irreversibility of potential damage. The precautionary principle is the formal embodiment of this age-old wisdom.

In fact, most histories of the Precautionary Principle begin by referring to early German household management principles ("Vorsorgeprinzip", literally precautionary principle in English).[1] However, the Precautionary Principle of environmental law and policy covers a narrower area than what is generally understood by the notion of exercising precaution. The Principle's specific objective is tackling scientific uncertainty in relation to threats to the environment or human health, caused by human activity.[2]It is to be triggered, ideally, when the risk associated with an activity is not estimable – either by reason of uncertainty relating to the likelihood of the damage occurring, or to the propensity of damage, or both.[3] If the risk were estimable, Law and economics would suggest considering them as externalities to be included as social costs in cost-benefit analysis. Eventual action of either prevention or insurance can be determined on the basis of cost-benefit analysis. In other words, the Principle concerns risks that are not easily addressed by standard prevention or insurance activities, which ultimately rely on some sort of cost-benefit analysis.[4]

In the 30 odd years since its articulation in the Rio Declaration on environment and development (1992), it has been incorporated in various international treaties, supra-national and national legislation, and policy in varying degrees of bindingness. However, there still remain debates as to its efficacy and desirability. Even as its proponents and its critics continue to put forth arguments as to its necessity and its pitfalls respectively, there still remains a question as to whether and what role it plays in actual decision-making relating to

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[1] O'Riordan, T. (2013). Interpreting the precautionary principle. Routledge, 12.
[2] O'Riordan, T. (2013). Interpreting the precautionary principle. Routledge,16.
[3] Von Schomberg, R. (2012) The precautionary principle: Its use within hard and soft law. European Journal of Risk Regulation. 2: 147–156.
[4] Treich, N. (2001). What is the economic meaning of the precautionary principle? The Geneva Papers on Risk and Insurance. Issues and Practice, 26(3), 334-345.

uncertain serious threats to the environment or human health. Accordingly, this thesis undertakes a positive analysis of the operationalization and impacts, explicit or implied, of the precautionary principle in a case of scientific uncertainty.

To that end, this introductory chapter intends to give a brief overview of the thesis by setting up the background, the research question(s), the scope, the structure and relevance of the thesis.

1.1 Background

The formal conceptualization of the Precautionary Principle in the Rio Declaration of 1992[5] marks a watershed moment in international law as regards addressing uncertainties and incomplete knowledge.[6] It was the first time that incompleteness of knowledge regarding environmental consequences was formally acknowledged as a problem that decision-makers would have to contend with.[7] However, even after a seemingly long period post introduction there doesn't appear to be one answer as to what it practically entails and when (what threshold of uncertainty) should it be triggered, which form of the approach is to be preferred etc. Nevertheless, some convergence on the necessary components and guidelines as to its implementation has been reached. The three most frequently used definitions- the ones formulated under the Rio Declaration[8], the Wingspread Conference(1998)[9] and the European Union's Commission on the Precautionary Principle(2000)[10]- while appearing different (in terms of the cost-effectiveness of proposed measure) converge on the view that insufficient, inconclusive or uncertain scientific evidence is to be tolerated when preliminary scientific

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[5] Principle 15, Rio Declaration on Environment and Development, 1992 United Nations "Conference on Environment and Development" (UNCED).

[6]Science for Environment Policy (2017) The Precautionary Principle: decision making under uncertainty. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol. Available at: http://ec.europa.eu/science-environment-policy.

[7] Sandin, P. (1999). Dimensions of the precautionary principle. Human and Ecological Risk Assessment: An International Journal, 5(5), 889-907.

[8] "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."

[9] Definition articulated on the basis of Statements made in Wingspread Conference on The Precautionary Principle, January 26, 1998: "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…The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action..."

[10] "The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU"

evaluation indicates threat of serious or irreversible or morally unacceptable harm. The principle is further guided in many instances by requirements of adherence to principles of proportionality, consistence, periodic review based on updated scientific knowledge and tests such as the hypothetical risk or trivial uncertainty.[11]

Several economic justifications have been propagated to support the relevance of the principle. Kolstad (1990)[12] explains it as adding to the Shavell[13] 's criteria of when regulatory standards are to be preferred to liability rules. Wibisana(2000)[14] provides a comprehensive analysis of the economic justifications for the precautionary principle drawing on ideas of precautionary principle as an uncertainty premium (Kuntz-Duriseti ,2004)[15], extension of the quasi-option value to an inter-temporal dimension(based on the Arrow and Fisher model, 1974)[16] impact of prospect of improving knowledge on the decision-maker's level of prevention (Gollier et al, 2000)[17] as well as it being grounded in the strategy of minimax-regret whilst playing games with nature (Gardiner, 2005)[18] .

Even as the evolution of guidelines and increasing acceptance globally is gradually elevating the principle to be part of international customary law[19], the criticisms levelled against it continue to gather force as well. The main charges levelled against the precautionary principle are that it is too vague to implement as reasonable standards[20] , marginalizes

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[11] Science for Environment Policy (2017) The Precautionary Principle: decision making under uncertainty. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol. Available at: http://ec.europa.eu/science-environment-policy

[12] Kolstad, C.D; T. S. Ulen; and G.V. Johnson. 1990. "Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes of Complements?". The American Economic Review, Vol. 80, No. 4, pp. 888-901.
[13] Shavell, S. 1987. Economic Analysis of Accident Law. London: Harvard University Press.
[14] Wibisana, M. R. A. G., and Andri Gunawan. "Law and economic analysis of the precautionary principle." *Desertasi Doktor Maastricht University, Maastricht* (2008).
[15] Kuntz-Duriseti, K. 2004. "Evaluating the Economic Value of the Precautionary Principle: Using Cost-benefit Analysis to Place a Value on Precaution". Environmental Science and Policy, Vol. 7, No. 4, August, pp. 291-301.
[16] Arrow, K.J. and A. Fisher. 1974. "Environmental Preservation, Uncertainty, and Irreversibility". The Quarterly Journal of Economics, Vol. 88, Issue 2, May, pp. 312-319.
[17] Gollier, C.; B. Jullien; and N. Treich. 2000. "Scientific Progress and Irreversibility: An Economic Interpretation of the 'Precautionary Principle'". Journal of Public Economics, Vol. 75, pp. No. 2, pp. 229-253
[18] Gardiner, S. "A Core of Precautionary Principle". Available at: <http://faculty. washington.edu/ smgard/CPPWeb.pdf>. Accessed in July 2005.
[19] Farber, D. A. (2015). Coping with Uncertainty: Cost-Benefit Analysis, The Precautionary Principle, and Climate Change, 90 Wash. *L. Rev*, *1659*, 1694-95.
[20] Bodansky, D. (1991). Law: scientific uncertainty and the precautionary principle. *Environment: Science and Policy for Sustainable Development*, *33*(7), 4-44.

scientific decision making[21] and enables value judgements of few to prevail as higher-order standards.[22]

The discontent (at the core of it) arises from the political discretion that the principle allows to operate on allegedly scientific decisions- that value judgements are being made by non-scientists with too vague a standard legitimizing them. Adler (2011)[23] argues, "*democratizing decisions about the acceptability of given technologies or marketplace transactions involves supplanting the decisions of those most involved through a political process. There is no guarantee this ensures adequate representation of those most affected or produces a more precautionary or environmentally protective result.*"

Further criticism stems from the risk-aversion encouraged by the precautionary principle. Critics argue that an uncertain threat would be perceived as a greater threat than it actually might be, and the immediate need to protect against it can result in ignoring the risk/risk trade-off involved in any precautionary measure.[24] Excessive precaution can also lead to a risk-averse bureaucracy, innovators discouraged by the cost of proving the absence of harm and an eventual technological standstill.[25] Furthermore, in appearing as protectors against uncertain serious damage, the governmental agencies might gain enough trust from the public so as to embolden them to regulate beyond their competencies without any checks or balances.[26]

1.2 Research questions

The discussion till now has set forth the theoretical underpinnings of the advantages and criticisms of the precautionary principle. Both these aspects will be discussed in further detail in the next chapters of the thesis. Despite the development of these theories, the actual role

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[21] Chapman, P. M. (1999). Does the precautionary principle have a role in ecological risk assessment? *Human and Ecological Risk Assessment: An International Journal*, *5*(5), 885-888.
[22] Charnley, G. (2000). 1999 Annual Meeting. Past President's Message: Risk Analysis under Fire. *RISK newsletter*, *20*(3).
[23] Adler, J. H. (2011). The problems with precaution: A principle without principle.
[24] Graham, J. D., & Wiener, J. B. (2008). The precautionary principle and risk–risk trade-offs: a comment. *Journal of Risk Research*, *11*(4), 465-474.
[25] Nollkaemper, A. (1996). What you risk reveals what you value, and other dilemmas encountered in the legal assaults on risks. *The Precautionary Principle and International Law: The Challenge of Implementation. Kluwer Law International, The Hague*, 73-94.
[26] Sunstein, C. R. (2005). The precautionary principle as a basis for decision making. *The Economists' Voice*, *2*(2).

played by the precautionary principle and the extent of its impact on decision-making still remains unclear. Consequently, the primary research question of this thesis is:

- What role does the precautionary principle play in decisions regarding uncertain threats?

The question itself, though not a Law and Economics question, arises from a Law and economics concern. As mentioned earlier, externalities, even when uncertain, are sought to be accounted for by including them as social costs (with the dimensions of probability of occurrence and magnitude) when assessing the economic efficiency of a measure. Cost-benefit analysis (CBA) is most preferred on economic grounds, as a way of promoting economic efficiency and thus eliminating unnecessary and wasteful public and private expenditures.[27] Furthermore, it can be understood as a way of diminishing interest-group pressures on regulation and also as a method for ensuring that the consequences of regulation are not shrouded in mystery but are instead made available for public inspection and review.[28]

Considering that the precautionary principle aims to fill the gaps in the CBA, understanding the role played by the principle in actual practice will shed light on the nature of these gaps and open the discussion for the possibility of expanding or adapting the CBA itself to address the gaps. Furthermore, it will also help understand if uncertainty is currently being allocated in a similar manner as to risk-allocation.

The research question, in itself comprises of three different aspects. To begin with, it is not necessary that the precautionary principle play any role at all in such decision-making. It may be the case that administrative bodies and risk managers continue to handle uncertainty within existing risk analysis frameworks (quantitative or otherwise) and there is no operationalization of the precautionary principle at all. Thus, the first aspect to be examined is:

[27] Torriti, J., Ikpe, E. (2014). Cost–Benefit Analysis. In: Backhaus, J. (eds) Encyclopedia of Law and Economics. Springer, New York, NY. https://doi.org/10.1007/978-1-4614-7883-6_124-1
[28] Torriti, J., Ikpe, E. (2014). Cost–Benefit Analysis. In: Backhaus, J. (eds) Encyclopedia of Law and Economics. Springer, New York, NY. https://doi.org/10.1007/978-1-4614-7883-6_124-1

- Has the precautionary principle been explicitly relied upon in a decision involving an uncertain threat?

Secondly, it must be recognized that the precautionary principle could, nevertheless, have an implied impact on the decision or the regulatory process even if there has been no explicit invocation of the principle. For this implied impact to be relevant as that caused by the precautionary principle, it needs be an outcome or process that would not have resulted in the absence of the precautionary principle i.e. it has to be an addition to the existing risk analysis framework. Accordingly, the second aspect to be examined is:

- Does the precautionary principle have an implied value-addition to the decision-making process regarding uncertain threats?

Lastly, it is important to study if any of the criticisms of the precautionary principle can be seen to occur, even if the previous two questions yield a negative answer. It could happen that in addition to not adding value to the decision-making process, the precautionary principle rather detracts value from it. Thus, the third aspect to be examined is:

- Do the criticisms of the precautionary principle impact the decision-making process regarding uncertain threats?

The decision under question in all three is the glyphosate authorisation in the EU. As such, a more specific research question for the thesis is what role has the precautionary principle played in decisions relating to the uncertain threat posed by glyphosates?

1.3 Scope and methodology

The thesis examines the aspects described above using as a case study the decision relating to reauthorization of glyphosates in the EU and the subsequent response by Member-states at the national level, spanning 2015 to 2023. As such, an empirical discussion in the form of a case study underpins the thesis.

The EU level decision is studied in 2 manners – using a qualitative Law and Economics analysis (after establishing an ideal rule scenario) and through a public choice lens. A comparative study has been done of the Member-state decisions, establishing baseline comparison points using the EU level decision analysis.

The specific case study of glyphosates lends itself suitable for the research due to a combination of reasons. First, it is a suitable case for invocation of the precautionary

principle as there is substantial divergence in scientific opinion as regards the possibility of it being carcinogenic for humans (i.e. uncertainty as to serious threat to human health). Second, the vital role played by glyphosates in the agriculture industry and maintaining food supplies means that the regulation of any threat posed by glyphosates, uncertain or not, would require a delicate balancing of competing interests. This allows for greater opportunity to examine how the third aspect of the research question plays out in actual decision-making. Lastly, the structure of pesticide regulation within the EU creates different opportunities for regulation of the same uncertain threat at various levels of government. Consequently, it allows for a more comprehensive comparison of the extent of the impact of the precautionary principle as also to highlight what other factors may play a role in shaping risk management decisions.

Whilst studying the individual cases, an approach similar to that outlined in the RECIPES (REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders) project [29] will be adopted. To this end, the glyphosate authorization decision by the European Commission and within the countries of France, Netherlands and Germany will be studied in the context of the legal underpinnings, the existing policy towards pesticides and the reasons for the existing regulatory regime and the specific decision relating to glyphosates. In evaluating the decisions, they will be analyzed to determine if there was an explicit reliance on the precautionary principle, if any deviation from usual outcomes can be attributed to an implicit reliance on the precautionary principle and if any of the criticisms of the precautionary principle can be seen in the decision-making process.

1.4 Structure

The thesis comprises of 7 chapters including the present introductory chapter. The remaining chapters are structured as follows:

- Chapter 2: Precautionary Principle

The chapter discusses the background for the emergence of the precautionary principle and goes on to understand the convergence in the various definitions of the principle. It identifies 4 common dimensions that form a part of any definition of the precautionary principle. The scope of application of the principle is discussed by making a distinction between risk and

[29] Joe Rini (IASS Potsdam) WP2 Conceptual framework for comparative multiple case study analysis, December 4, 2019. The RECIPES project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824665

uncertainty and establishing the legal standing of the principle within EU law. Finally, the intended value addition of the principle as regards decision-making as also in shaping regulatory processes is discussed.

- Chapter 3: Criticisms of the Precautionary Principle

The chapter discusses the criticism levelled against the precautionary principle. The criticism is explained as stemming from two different categories of criticism: firstly, as regard the principle as a decision-making rule being too vague and marginalizing scientific decisions; secondly, in relation to the impact it could have on the regulatory process causing risk/risk trade-offs to be neglected, encouraging a risk averse bureaucracy and eventual technological standstill, and enabling regulatory over-reach.

- Chapter 4: Analyzing the role of the precautionary principle in the EU's decision to renew authorization for glyphosate as an active ingredient

The chapter begins by summarizing the timeline of the decision to help explain why the glyphosate case would be suitable for the application of the precautionary principle. It further delves into explaining the reasons as to why there exists a divergence of scientific opinion and consequent uncertainty regarding the potential threat posed by glyphosates. Having thus shown the suitability of application of the precautionary principle, the chapter goes on to assess the role of the precautionary principle in the decision by the European Commission as a whole. A further section of the chapter then disentangles the Member State response at the EU level. As part of this section, an overview of member state response at national level helps to elucidate risk concerns as also establishes the relevancy of Member State case studies for examining the glyphosate decision.

- Chapter 5: Intermezzo

An *intermezzo* chapter identifying the questions for the subsequent case studies, establishing the structure and sources of information of the case studies and explaining the choice of countries.

- Chapter 6: Case studies of national responses to glyphosate in plant protection products

The chapter analyses individually and in comparison, with each other the national responses of France, Germany and the Netherlands to pesticides with glyphosate as their active ingredient. The responses are analyzed for consistency with their EU level stance, their own

pesticide policy, the precautionary principle and whether the responses balanced the risk and benefit involved.

- Chapter 7: Conclusion

A concluding chapter to draw insights and implications from the analysis in the previous chapters. The chapter explains how the precautionary principle in its current formulation does not add or detract much from the existing risk regulatory framework. The chapter goes on to suggest what could be a more meaningful role that the precautionary principle could play in facilitating better risk communication.

1.5 Societal and Scientific contribution

Primarily, the thesis adds to the debate on the precautionary principle. Even though a lot has been written on the precautionary principle, the thesis supplements this ongoing discussion with insights about its actual role in practice. The discussion tends to take the form of a binary choice about the desirability of the precautionary principle. This thesis questions not just its effectiveness in serving its intended purpose but if the criticism levelled against it is warranted. The conclusions of the thesis will allow for a more tempered and nuanced discussion around the principle and set up the foundation for possible changes in its application. Additionally, it also establishes a structure for future analysis of decisions where the precautionary principle might be deemed applicable (e.g. neonicotinoids).

Furthermore, by using the example of glyphosates (a product where uncertainty persists despite considerable research and data since the 1970s), it helps to highlight situations where uncertainty could persist despite availability of data and means of testing. Through a comparative study of risk assessments, it elucidates possible changes to reduce such divergence in nomenclature and baseline assumptions in risk management decisions. In doing so, it emphasizes the necessity for a better understanding of subjective assumptions that underpin seemingly objective assessments.

The comparative study of the response to an uncertain threat adds to the overall information on behavioural patterns in risk-regulation. The effect of uncertainty on the perception of risk by the public at large has been compared in different national contexts. At the same time, it also shows if bureaucracy exhibits similar risk-aversion (as theorized under public choice) in reaction to this different perception, when the threat is uncertain.

Lastly, as the decision of the countries has been studied at the EU level and national level, the thesis is also relevant as an example of how the intensity to counter the same threat might differ at different federals levels.

Chapter 2: The Precautionary Principle-Its Nature Scope and Legal Implications

2.1 Introduction

This initial chapter of the thesis aims to elaborate and establish the existing understanding and legal standing of the precautionary principle. The chapter intends to set forth the baseline as to the principle's scope, intended application and the regulatory actions it allows within the institutions whose decisions will be analyzed further in the thesis. Furthermore, it provides a brief overview of the varied modes of its operationalization.

To begin with, the first part of the chapter discusses the most prevalent definitions of the principle and the common dimensions that can be observed in all of the definitions. The next part discusses the scope of application of the precautionary principle. In doing so, on the one hand it delves deeper into the distinction between uncertainty and risk and the kinds of uncertainty that would invite the application of the principle. On the other hand, the part also elaborates on the evolution of the intended use of the principle– as a decision-making guideline and as a regulatory procedure. The final part of the chapter discusses the legal standing of the Principle within European Union law.

2.2 What is the precautionary principle?

2.2.1 Definitions

The Precautionary principle was developed in environmental law as a means to assist with avoiding serious or irreparable but uncertain harm to human health or the environment.[30] It's specific objective is tackling scientific uncertainty in relation to threats to the environment or human health, caused by human activity.[31] Such uncertainty could refer to incomplete knowledge as regards either propensity or probability of damage or both.[32] The lack of knowledge could result from not enough research at the moment or also an insufficiency of resources to collect adequate data.[33] Thus, the Principle comes into play when risk assessment

[30] Science for Environment Policy (2017) The Precautionary Principle: decision making under uncertainty. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol. Available at: http://ec.europa.eu/science-environment-policy.
[31] O'Riordan, T. (2013). Interpreting the precautionary principle. Routledge,16.
[32] Von Schomberg, R. (2012) The precautionary principle: Its use within hard and soft law. European Journal of Risk Regulation. 2: 147–156.
[33]

frameworks which ultimately rely on some sort of cost-benefit analysis requiring such information cannot be utilized.[34]

Indeed, the formal conceptualization of the Precautionary Principle in the Rio Declaration of 1992[35] is a decisive and purposeful acknowledgement of the need to address uncertainties and incomplete knowledge.[36] It was the first time that incompleteness of knowledge regarding environmental consequences was formally acknowledged as a problem that decision-makers would have to contend with.[37] However, even after a seemingly long period post introduction there does not appear to be one answer as to what it practically entails, when (at what threshold of uncertainty) it should be triggered, which form of the approach is to be preferred, etc.[38] Nevertheless, some convergence on the necessary components and guidelines as to its implementation has been reached.

The first official statement of the Principle in the Rio Declaration of 1992[39] stated

"*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."*

Following this statement, the principle was further incorporated into international, supra-national and national legislations, as also elaborated upon by academicians across the world. Apart from the Rio Declaration, the two most frequently relied upon definitions are:

The definition articulated based on the discussions in the Wingspread Conference (1998)[40]:

"*When an activity raises threats of harm scientifically…The process of applying the Precautionary Principle must be open, informed, and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action...to human health or the environment, precautionary*

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[34] Treich, N. (2001). What is the economic meaning of the precautionary principle? The Geneva Papers on Risk and Insurance. Issues and Practice, 26(3), 334-345.
[35] Principle 15, Rio Declaration on Environment and Development, 1992 United Nations "Conference on Environment and Development" (UNCED).
[36] Raffensperger, C., & deFur, P. L. (1999). Implementing the precautionary principle: Rigorous science and solid ethics. Human and Ecological Risk Assessment: An International Journal, 5(5), 933-941.
[37] O'Riordan, T. (2013). Interpreting the precautionary principle. Routledge, 16.
[38] The problems with precaution: A principle without principle; Charnley, G. (2000). 1999 Annual Meeting. Past President's Message: Risk Analysis under Fire. RISK newsletter, 20(3).
[39] Principle 15, Rio Declaration on Environment and Development, 1992 United Nations "Conference on Environment and Development" (UNCED).
[40] Ashford, N., Barrett, K., Bernstein, A., Costanza, R., Costner, P., Cranor, C., ... & Warledo, J. (1998). Wingspread statement on the precautionary principle.

measures should be taken even if some cause-and-effect relationships are not fully established."

And the definition given in the communication by the European Union's Commission on the Precautionary Principle (2000)[41]

"*The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU.*"

2.2.2 Dimensions of the precautionary principle

Certain points of convergence can be identified in all the different formulations of the Precautionary Principle[42], namely- threat, uncertainty, action, and command. All definitions of the principle are formulated in the manner of 'if threat and uncertainty exist, then action is commanded.' How each of these dimensions are phrased in a particular definition consequently determines the degree of cautiousness implemented by that definition and the legal standing of the principle in that system.[43] To better understand how this determination works, following is a brief discussion on the meaning of each dimension and its potential variations.

- ***Threat dimension***

The threat dimension refers to undesired possible states of the world. Such threats are generally anthropogenic[44] and possess three aspects of severity, reversibility (or lack thereof) and preventability.[45] Thus, a particular definition of the Precautionary Principle would use these three markers to describe the kind of threat that would invite the principle's application.

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[41] Science for Environment Policy (2017) The Precautionary Principle: decision making under uncertainty. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol. Available at: http://ec.europa.eu/science-environment-policy.
[42] Sandin, P. (1999). Dimensions of the precautionary principle. Human and Ecological Risk Assessment: An International Journal, 5(5), 889-907, 893.
[43] Sandin, P. (1999). Dimensions of the precautionary principle. Human and Ecological Risk Assessment: An International Journal, 5(5), 889-907, 891.
[44] Hansson, S. O. 1997. The Limits of Precaution. Foundations of Science 2, 293–306.
[45] Fleming, D. 1996. The Economics of Taking Care. In: The Precautionary Principle and International Law: The Challenge of Implementation, pp. 147–167. (Freestone, D. and Hey, E., Eds.). The Hague: Kluwer Law International.

For instance, the Rio Declaration requires a 'threat of serious or irreversible damage' whereas the Deville and Harding framework[46] for Australian public officials requires regulation in case of a 'threat of non-negligible harm, especially if irreversible'. Clearly, the Australian framework applies the principle in case of smaller threats as compared to the Rio Declaration. Therefore, it can be argued that the Australian framework based on the reading of the threat dimension has defined the Precautionary Principle in a more cautious manner.

- ***Uncertainty dimension***

The second dimension, uncertainty, expresses the lack of knowledge regarding possible threats of any activity. The uncertainty dimension states how scientifically plausible a threat must be in order to trigger precaution. In effect, it establishes the minimum consensus or scientific evidence necessary to consider exercising precaution.[47]

In specifying such a minimum threshold, it could limit the spheres in which lack of knowledge can be allowed. This specification is indicated by phrases like 'insufficient evidence as to impact', 'even if causal link not fully established'.[48]

On the other hand, it could also require a quantifiable consensus among experts. Such a requirement is stated using phrases such as '70% of the eminent scientists in the discipline should regard it an imminent threat'. [49]Similar to the analysis of the threat dimension, it can be argued here that definitions of the Precautionary Principle that establish a lower threshold of minimum evidence required for a threat to be plausible are the ones adopting a more precautionary approach.

- ***Action dimension***

The third dimension concerns the form of response prescribed to deal with a potential threat. As it relates to the action to be taken in response to a threat, it has been termed as the action dimension. Most formulations of the Precautionary Principle do not have very specific

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[46] Deville, A., & Harding, R. (1997). *Applying the precautionary principle*. Federation Press.
[47] Sandin, P. (1999). Dimensions of the precautionary principle. Human and Ecological Risk Assessment: An International Journal, 5(5), 889-907, 894.
[48] Ashford, N., Barrett, K., Bernstein, A., Costanza, R., Costner, P., Cranor, C., ... & Warledo, J. (1998). Wingspread statement on the precautionary principle.
[49] Note: there are no prominent examples of such specific wording for the uncertainty dimension, even if it remains a possibility.

phrases prescribing actions; they are intended to be general and adaptable, consistent with the higher-order normative character of the principle.[50]

The fact that the action is rarely specified makes it difficult to use the action dimension to compare the degree of cautiousness exercised by different formulations. In fact, whenever only a solitary action is specified as an appropriate response, it may indicate that the scope of the Precautionary Principle is limited in that particular definition. [51]

- ***Command dimension.***

The fourth and final dimension, the command dimension, states the legal status of the action: for example, if the action is allowable, justified, recommended, or mandatory.[52] Admittedly, the variations in the command dimension do not allow for easy comparisons of the degree of cautiousness like the threat or uncertainty dimensions. Nevertheless, they play a determining role in allocating risk, responsibility, and access to decision-making.[53]

Based on the command dimension, the literature loosely classifies the formulations of the principle into having a prescriptive or argumentative character.[54] Prescriptive formulations refer to those that mandate an action. In such cases, the onus of decision-making is on the public body required to perform such action. Failure to perform such action can result in censure to varying degrees. Thus, public bodies bear the responsibility to proactively exercise a precautionary approach in policymaking and implementation.[55]

On the other hand, argumentative formulations merely serve to provide a means of legitimacy for an additional regulatory action.[56] Here, the public body does indeed enjoy greater access to decision-making but there is a corresponding burden to justify their decisions within the

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[50] Morris, J. 2000. 'Defining the Precautionary Principle', in J. Morris (ed.) Rethinking Risk and the Precautionary Principle (Oxford: Butterworth-Heinemann), pp. 1-21.
[51] Sandin, P. (1999). Dimensions of the precautionary principle. Human and Ecological Risk Assessment: An International Journal, 5(5), 889-907, 899.
[52] Grandjean, P., Bailar, J. C., Gee, D., Needleman, H. L., Ozonoff, D. M., Richter, E.,…Soskolne, C. L. (2004). Implications of the Precautionary Principle in research and policy-making. American Journal of Industrial Medicine, 45(4), 382–385. https://doi.org/10.1002/AJIM.10361; Norwegian Gene Technology Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organism; EU REACH Regulation (EC) No. 1907/2006; Sandin, P., Peterson, M., Hansson, S. O., Rudén, C., & Juthe, A. (2002). Five charges against the precautionary principle. Journal of Risk Research, 5(4), 287-299.
[53] Geistfeld, M. (2001). Implementing the precautionary principle. Environmental Law Reporter, 31.
[54] Von Schomberg, R. (2012) The precautionary principle: Its use within hard and soft law. European Journal of Risk Regulation. 2: 147–156, 150
[55]Geistfeld, M. (2001). Implementing the precautionary principle. Environmental Law Reporter, 31.
[56] Morris, J. 2000. 'Defining the Precautionary Principle', in J. Morris (ed.) Rethinking Risk and the Precautionary Principle (Oxford: Butterworth-Heinemann), pp. 1-21.

parameters of the Precautionary Principle.[57] However, unlike with the prescriptive formulations, there is no burden on the public authorities to actively implement the principle.[58]

Within the argumentative formulations of the command dimension, there is a frequently observed variation that follows from the reversal of burden of proof.[59]Generally, law and scientific methods place the burden of proof on those alleging an activity to be harmful.[60] However, under the Precautionary Principle, it may sometimes be possible to reverse this requirement.[61] In essence, it would allow a potentially harmful activity to be questioned and possibly delayed till it is satisfactorily shown to be harmless.

[57] Sandin, P., Peterson, M., Hansson, S. O., Rudén, C., & Juthe, A. (2002). Five charges against the precautionary principle. Journal of Risk Research, 5(4), 287-299.
[58] Sandin, P. (1999). Dimensions of the precautionary principle. Human and Ecological Risk Assessment: An International Journal, 5(5), 889-907.
[59] Geistfeld, M. (2001). Implementing the precautionary principle. Environmental Law Reporter, 31.
[60] Bodansky, D. (1991). Law: scientific uncertainty and the precautionary principle. Environment: Science and Policy for Sustainable Development, 33(7),
[61] Geistfeld, M. (2001). Implementing the precautionary principle. Environmental Law Reporter, 31.

Table 2.1 Varied terms used in various definitions of the precautionary principle[62]

Threat	Uncertainty	Action	Command
○ Potentially dangerous actions ○ Possible risks ○ Identified risks ○ Non-negligible harm ○ Activity raising threats to the environment or human health ○ In some way non-negligible environmental risks being run by not regulating ○ Threats of serious or irreversible damage ○ Significant risks of damage to the environment ○ Human interventions in environmental sectors that are unusually susceptible to significant injury, especially irreversible injury	○ In some way uncertain ○ Unusually short on scientific understanding ○ Scientific evidence is not conclusive ○ Before full scientific proof is established ○ Strong scientific evidence on causal relationships or the extent of damage is missing ○ Lack of scientific proof of cause and effect ○ Some cause-and-effect relationships are not fully established scientifically ○ Lack of full scientific certainty ○ Before a causal link has been established by absolutely clear scientific evidence ○ Lack of scientific certainty on the cause-and-effect relationships	○ Action to protect the environment ○ Measures to prevent environmental degradation ○ Limit, regulate or prevent ○ Regulatory action/regulatory inaction ○ Regulatory measures ○ Cautious and conservative approach to human interventions ○ Precautionary measures ○ Cost-effective measures to prevent environmental degradation ○ Precautionary action to limit the use of potentially dangerous materials or the spread of potentially dangerous polluters	○ Is mandatory ○ Should be taken ○ Is required ○ Is a premium on ○ Is justified ○ May be required ○ Not acting is not justified ○ May be justified ○ (uncertainty) shall not be used as an argument for postponing ○ (the Government) will be prepared to act if the balances of likely cost and benefits justifies it

- ***Additional caveats***

Apart from the common dimensions discussed above, the principle is further guided in many instances by caveats that help ensure a fair procedure. These caveats have been a response to the criticism that the principle allows for too much discretion and subjective risk-evaluations.[63] By requiring the decision- making process to be non-arbitrary, consistent and subject to periodic review based on updated scientific knowledge, policymakers have tried to minimize the chance of outcomes being influenced by personal or political motivations.[64] Most definitions also contain a reference to cost-effectiveness and proportionality of a

[62] Sandin, P. (1999). Dimensions of the precautionary principle. Human and Ecological Risk Assessment: An International Journal, 5(5), 889-907.
[63] Sandin, P., Peterson, M., Hansson, S. O., Rudén, C., & Juthe, A. (2002). Five charges against the precautionary principle. Journal of Risk Research, 5(4), 287-299
[64] Jiang, P. (2014). A uniform precautionary principle under EU law. Peking U. Transnat'l L. Rev., 2, 490.

response devised under the principle. Some of the definitions may further go on to lay guidelines or procedures regarding how such proportionality is to be assessed.[65]

2.3 Scope of application

2.3.1 Uncertainty as understood in the Precautionary Principle

Though there are variations in formulating the Precautionary Principle, the term 'uncertainty' used in the principle is seen to have the same meaning throughout. It has been discussed in the earlier section as one of the common dimensions in the various definitions of the principle. Nevertheless, a discussion about what the term exactly refers to would be beneficial to clarify the operational area and added value of the Precautionary Principle.

Uncertainty refers to the lack of scientific knowledge regarding the possibility or intensity of damage that could be caused by a proposed change to the environment.[66]Such a change could be the direct result of a new project or product as well as the result of a new policy or legislation. Furthermore, the lack of scientific knowledge might be either due to insufficient research because of logistical reasons or even due to substantial disagreement in the scientific community in that realm.

The notion of uncertainty described above must be distinguished from that of risk. Knight (1921)[67] identifies risk and uncertainty as distinct problems faced by a decision-maker (albeit in relation to financial matters). Accordingly, strategies to combat them are also distinct from each other. On the one hand, combating risk is a static concept involving the management of a risk at a given time and a stable probability distribution- the extent of damage and probability of such damage occurring are both known. Such risk requires prevention strategies to mitigate its damage. On the other hand, dealing with uncertainty is dynamic in nature- it involves situations where the current lack of scientific evidence results in not knowing both the probability and the extent of damage. A precautionary approach is warranted in the latter to allow for a prudent but flexible strategy.

A further facet to understanding uncertainty relates to how this concept gets interpreted in the legal sphere. Law requires causal links to be established fully and sufficiently to accept cause

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[65] Jiang, P. (2014). A uniform precautionary principle under EU law. Peking U. Transnat'l L. Rev., 2, 490.
[66] Science for Environment Policy (2017) The Precautionary Principle: decision making under uncertainty. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol. Available at: http://ec.europa.eu/science-environment-policy.
[67] Knight, F. H. (1971). Risk, uncertainty and profit, 1921. *Library of Economics and Liberty*.

and effect between two events – this could be for assigning liability or justifying regulation.[68] Thus, bearing this legal requirement of causation in mind, the concept of uncertainty can be understood in an additional manner. It would, then, also refer to situations where there is insufficient evidence to establish causation.[69]

A final note of caution to bear in mind as regards the above discussion is that not every fanciful possible consequence can be termed as an uncertain consequence.[70] To be considered under the precautionary principle, uncertain consequences still must have some plausible basis. Thus, uncertainty refers to insufficiency of data or details concerning a consequence and not the absence of any basic data or theory predicting such a consequence.

2.3.2 Intended uses of the precautionary principle

- ***Higher order principle***

Initially, the precautionary principle was presented by way of being a higher order principle, and not a set of brightline rules.[71] It was intended to operate as a reference point in a harmonization process allowing for empirical diversity and variations.[72] It served to articulate agreed social values, recognize acceptable forms of action and ultimately, stimulate change in an existing normative system.[73]In this iteration, it was understood as reflecting the value judgement that protection of the environment and human health trumps quantitative measures of risk and economic efficiency.[74]

It is worthwhile to revisit the literature regarding rules vs standards to understand why the precautionary principle may have so been devised. Rules are those legal commands which differentiate legal from illegal behavior in a simple and clear way. Standards, however, are general legal criteria which are unclear and fuzzy and require complicated judiciary decision making.[75] For the choice between rules and standards, the promulgation, adjudication and

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[68] Geistfeld, M. (2001). Implementing the precautionary principle. Environmental Law Reporter, 31.
[69] Morris, J. 2000. 'Defining the Precautionary Principle', in J. Morris (ed.) Rethinking Risk and the Precautionary Principle (Oxford: Butterworth-Heinemann), pp. 1-21.
[70] Jiang, P. (2014). A uniform precautionary principle under EU law. *Peking U. Transnat'l L. Rev.*, *2*, 490.
[71] Ahteensuu, M. (2007). Defending the precautionary principle against three criticisms. *Trames*, *11*(4), 366-381.
[72] Sadeleer, N. D. (2006). The precautionary principle in EC health and environmental law. *European Law Journal*, *12*(2), 139-172.
[73] Godard, O. (2012). The Precautionary Principle and chemical risks. *The Philosophy of Chemistry: Practices, Methodologies, and Concepts*, 65-96.
[74] Applegate, J.S. (2002). The Taming of the Precautionary Principle. *William and Mary Environmental Law and Policy Review, 27*, 13.
[75] Schaefer HB. (2004) Legal Rules and Standards. In: Rowley C.K., Schneider F. (eds) The Encyclopedia of Public Choice. Springer, Boston, MA, 671.

compliance costs are decisive for a reduction of total costs.[76] Depending on the area they are being implemented, these costs are then influenced by volatility, complexity of reality, judge's specialization and frequency of application.[77] Considering the principle has to operate in the realm of scientific uncertainty, there is a complex reality and volatility to contend with. Such conditions provide a justification for the more general referential nature of the principle.

- ***Guideline for decision-makers***

As the principle continued to be incorporated in various subject- specific treaties[78] as also national legislations, it began taking on the form of a component of the general framework of risk analysis (which includes the phases of risk assessment, risk management and risk communication) and more particularly as one of the determining factors in the risk management phase that corresponds to the decision-making phase.[79]

The proponents of the principle argue that the precautionary principle in this form seeks to make decision-making more intellectually honest.[80]Centering policy-making around uncertainty, enables calling for more science instead of establishing slow-changing regulations based on bottom-line comparisons that do not present a complete picture.[81] Wibisana(2008)[82] provides a comprehensive analysis of the economic justifications for the precautionary principle drawing on ideas of precautionary principle as an uncertainty premium[83], impact of prospect of improving knowledge on the decision-maker's level of

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[76] Fon, V., & Parisi, F. (2007). On the optimal specificity of legal rules. *Journal of Institutional Economics*, *3*(2), 147-164.
[77] Kaplow, L. (1992). "Rules versus standards, an economic analysis." *Duke Law Journal*, 557–629.
[78] For instance : Stockholm Convention on Persistent Organic Pollutants, U.N. Env't Prog., art. 1, U.N. Doc. UNEP/POPS/CONF/2 (2001), 40 I.L.M. 532 [hereinafter POPS Convention]; Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, art. 1, 39 I.L.M. 1027 [hereinafter Cartagena Protocol]; Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, opened for signature June 24, 1998, pmbl., http://www.unece.org/env/ lrtap/pops hl.htm (last updated Dec. 5, 2002);
[79] Science for Environment Policy (2017) The Precautionary Principle: decision making under uncertainty. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol. Available at: http://ec.europa.eu/science-environment-policy.
[80] Raffensperger, C., & deFur, P. L. (1999). Implementing the precautionary principle: Rigorous science and solid ethics. *Human and Ecological Risk Assessment: An International Journal*, *5*(5), 933-941.
[81] Joel Tickner, Carolyn Raffensperger, The politics of precaution in the United States and the European union, Global Environmental Change, Volume 11, Issue 2, (2001), 175-180.
[82]Wibisana, M. R. A. G., "Law and economic analysis of the precautionary principle." *Desertasi Doktor Maastricht University, Maastricht* (2008).
[83] Kuntz-Duriseti, K. 2004. "Evaluating the Economic Value of the Precautionary Principle: Using Cost-benefit Analysis to Place a Value on Precaution". Environmental Science and Policy, Vol. 7, No. 4, August, pp. 291-301.

prevention[84] as well as it being grounded in the strategy of minimax-regret whilst playing games with nature[85].

Policymaking guided by the Precautionary Principle is seen to add to the scientific rigor in risk assessment by revising the questions asked, reversing the preferred type of error, shifting the information burden and establishing monitoring and performance bonds.[86]Reframing the questions of risk-assessment that attempt to, for instance, determine safety of novel technologies, the level of acceptable risk and level of contamination that ecosystems can assimilate without adverse effects is an honest acknowledgement of the limitations of science. In their stead, a precautionary approach would pose questions about the level of contamination that can be avoided, alternatives to the suggested technology that may be risk superior[87], the avenues of further research and monitoring occasioned by a new technology etc.

An argument advanced in favor of the Precautionary Principle as a decision-making tool is the contextual rationality[88] of its application i.e. in certain contexts, application of the Precautionary Principle can correct what would otherwise be a tendency to under-weigh the costs of not taking action to prevent or mitigate possible environmental and health risks.

Similarly, it is more rational in these contexts to set up evaluations that avoid false negatives and prefer false positives if required to choose between the two kinds of errors.[89] In statistical terms, it would mean increasing the statistical power of a test, setting an acceptable ecological effect size prior to setting the power of the test and requiring further questioning of whether the absence of a statistically significant effect in an investigation can be explained by other means.[90] Raffensperger and deFur (1999) argue that a preference for a false positive is also consistent with incentivizing the search for information. A false negative would lead to a

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[84] Gollier, C.; B. Jullien; and N. Treich. 2000. "Scientific Progress and Irreversibility: An Economic Interpretation of the 'Precautionary Principle'". Journal of Public Economics, Vol. 75, pp. No. 2, pp. 229-253
[85] Gardiner, S. "A Core of Precautionary Principle". Available at: <http://faculty. washington.edu/ smgard/CPPWeb.pdf>. Accessed on July 2005.
[86] Raffensperger, C., & deFur, P. L. (1999). Implementing the precautionary principle: Rigorous science and solid ethics. *Human and Ecological Risk Assessment: An International Journal*, *5*(5), 933-941, 936.
[87] Raffensperger, C., & deFur, P. L. (1999). Implementing the precautionary principle: Rigorous science and solid ethics. *Human and Ecological Risk Assessment: An International Journal*, *5*(5), 933-941, 937.
[88] Dana, D. (2009). The Contextual Rationality of the Precautionary Principle. *Queen's LJ*, *35*, 67.
[89] Sandin, P., Peterson, M., Hansson, S. O., Rudén, C., & Juthe, A. (2002). Five charges against the precautionary principle. Journal of Risk Research, 5(4), 287-299.
[90] Sanderson, H., & Petersen, S. (2002). Power analysis as a reflexive scientific tool for interpretation and implementation of the precautionary principle in the European Union. *Environmental Science and Pollution Research*, *9*(4), 221-226.

research dead end, but a false positive would incentivize proponents of a novel activity to pursue and share more information. It would help loosen information bottlenecks and allocate information costs on producers.

A corollary of the two points made above is the recognition of a need to monitor and update approved technologies, products etc. The absence of follow-up research once a technology or chemical has been released into the environment is one of the factors contributing to a lock-in and consequent slow retrenching on realizing the dangers. [91] For instance, responding to early red flags as to asbestos would have required following the efficacy and safety of the materials over the life of the materials. Responding to early alerts and red flags would have pushed for research into risk-superior alternatives.

- ***Shaping the regulatory process***

In recent times, the interpretation of the precautionary principle as a regulatory process rather than a decision-rule as suggested by Van Zwanenberg & Stirling (2003)[92] is gaining wider acceptance. As Wibisana (2008)[93] puts it, "*Rather than serve as a decision rule for low-probability high-consequences events, the precautionary principle represents greater recognition of uncertainty, ambiguity, and ignorance……. which are usually denied and concealed…. it could be argued that when implemented within a broader interpretation of incertitude, the precautionary principle serves as a way to support democratic and transparent risk-related policies, in which a wide range of disciplines and stakeholders are equally welcomed to participate in the policy making process."*

To a certain extent, this interpretation of its usefulness draws on its initial intended nature of a higher order principle to shape the decision-making phase of the risk analysis framework.

A further advantage of the principle when understood in this manner is that it helps to empower common citizens in voicing their concerns[94]. Advocates of the Principle argue that

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[91] Gee, D., MacGarvin, M., Stirling, A., Keys, J., Wynne, B., & Vaz, S. G. (2001). *Late lessons from early warnings: the precautionary principle 1896-2000*. P. Harremoës (Ed.). Luxembourg: Office for Official Publications of the European Communities.
[92] Van Zwanenberg, P. and A. Stirling. 2003. "Risk and Precaution in the US and Europe: A Response to Vogel". In: Somsen, H., et al. (eds.). The Yearbook of European Environmental Law, Vol. 3. Oxford: Oxford University Press, pp. 43-56.
[93] Wibisana, M. R. A. G... "Law and economic analysis of the precautionary principle." *Desertasi Doktor Maastricht University, Maastricht* (2008).
[94] Geistfeld, M. (2001). Implementing the precautionary principle. *Environmental Law Reporter*, *31*.

it results in access to decision-making being scattered amongst the actual potential victims.[95] Consequently, it helps to include their risk-preferences in the decision-making process. Additionally, the burden of information costs is to be borne by those privier to the information.[96]

2.4 Precautionary principle in the European Union: Communication on the precautionary principle (2000)

2.4.1 Treaty provisions and aim

Art. 191(2) of the Treaty on the Functioning of the European Union (TFEU) reads

"*Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."*

The precautionary principle is not defined in the Treaty; nevertheless, it is considered an autonomous principle inspired by the constitutional traditions in EU member states.[97] It developed as a general principle of Community law in the early 2000s, and was formally articulated by the European Commission's Communication on the Precautionary Principle,[98] and endorsed by the Council of Ministers' Nice Resolution.[99] The 2000 Communication on the Precautionary Principle explains the treaty provision, when recourse can be taken to the principle and establishes common guidelines for its application.

The stated aim under art 191 is to ensure a higher level of environmental protection and to enable a more rapid response to potential dangers threatening human, animal, or plant health.

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[95] Geistfeld, M. (2001). Implementing the precautionary principle. *Environmental Law Reporter*, *31*.
[96]Wibisana, M. R. A. G... "Law and economic analysis of the precautionary principle." *Desertasi Doktor Maastricht University, Maastricht* (2008).
[97] Garnett, K. and Parsons, D.J. (2017), Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law. Risk Analysis, 37: 502-516, 502. https://doi.org/10.1111/risa.12633
[98] EC. Communication from the Commission on the Precautionary Principle. Brussels: Commission of the European Communities, 2000.
[99]EC. Conclusions of the presidency adopted at the end of the European Council in Nice on 8 December 2000. Annex III, Resolution on the precautionary principle. *Bulletin of the European Union*, 2000; **12**: 8–30

Consequently, in practice, the scope of this principle has been seen to be wide enough to also impact consumer policy as also European Union (EU) legislation concerning food.[100]

Furthermore, the Communication also recognized that the definition of the principle could be relied on to ensure an appropriate level of environmental and health protection in international negotiations, *viz* the EU should push for inclusion of the precautionary principle as one of the guiding principles for international treaties relating to environmental protection.[101]

2.4.2 Recourse to precautionary principle.

In all instances, recourse to the precautionary principle is seen as part of the risk management phase and is available to the decision-making forums tasked with risk management decisions.

Three preliminary conditions have to be fulfilled to invoke the precautionary principle:

- identification of potentially adverse effects.
- such identification has to be based on an objective evaluation of the scientific data available.
- the available scientific data does not allow the risk to be determined with sufficient certainty.

2.4.3 Guidelines for application of the precautionary principle.

Depending on the level of risk identified, risk-managers are within their rights to enact a varied range of measures including stopping distribution or ordering the withdrawal of a product from the market, public information measures, financing of research programs etc. Whatever the context, the Communication sets forth some common guidelines for the application of the precautionary principle. Determination of appropriate precautionary measures must be informed by three specific principles:

- the fullest possible scientific evaluation, the determination, as far as possible, of the degree of scientific uncertainty.
- a risk evaluation and an evaluation of the potential consequences of inaction.

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[100] Garnett, K. and Parsons, D.J. (2017), Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law. Risk Analysis, 37: 502-516. https://doi.org/10.1111/risa.12633

[101] Science for Environment Policy (2017) The Precautionary Principle: decision making under uncertainty. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol. Available at: http://ec.europa.eu/science-environment-policy.

- the participation of all interested parties in the study of precautionary measures, once the results of the scientific evaluation and/or the risk evaluation are available.

In addition, any measure suggested has to be compliant with the general principles of risk management, *viz* proportionality, non-discrimination, consistency, examination of costs and benefits of action and lack of action, reviewing measures based on scientific developments. As a whole, judgments on proposed precautionary measures often include economic and legal factors, but rarely the full consideration of costs and benefits recommended by the Commission Communication.[102] A common consideration is the impact of national measures on the internal free market: precaution is not allowed to override other basic principles of the EU.[103]

In certain cases, particularly so in the case of medicines, pesticides and food additives, the producer, manufacturer, or importer may be required to prove the absence of danger from their product.[104] However, this reversal of the burden of proof may be a possibility only in a case-by-case basis and cannot be established as a general rule for all products of a certain kind.[105] The different standards of proof for invoking the precautionary principle, established in EU directives and regulations, suggest that grounds for invoking the precautionary principle may be dependent on what is at stake[106] - the greater the severity of harm , the lesser evidence as to its propensity to cause the harm is required. On the other hand, judicial interpretation of the principle tends to be restrictive, requiring plausible evidence of potential hazard in order to invoke precaution in the first instance.[107]

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[102] Garnett, K. and Parsons, D.J. (2017), Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law. Risk Analysis, 37: 502-516, 516. https://doi.org/10.1111/risa.12633
[103] Garnett, K. and Parsons, D.J. (2017), Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law. Risk Analysis, 37: 502-516, 516. https://doi.org/10.1111/risa.12633
[104] For instance, see: EC. Regulation (EC) No. 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No. 1601/91, Regulations (EC) No. 2232/96 and (EC) No. 110/2008 and Directive 2000/13/EC. *Official Journal of the European Communities*, 2008; **L 354**(31/12/2008): 34–50; ECJ. Judgment of the Court (Third Chamber) of 2 December 2004. Commission of the European Communities v Kingdom of the Netherlands. Failure of a Member State to Fulfil Obligations—Articles 30 and 36 of the EC Treaty (now, after Amendment, Articles 28 EC and 30 EC)—Foodstuffs to Which Vitamins or Mineral Salts Have Been Added—National Legislation Making Their Marketing Subject to There Being a Nutritional Need—Measures Having Equivalent Effect—Justification—Public Health—Luxembourg: European Court Reports, 2004; I–11375.
[105] Peter H. Sand (2000) The Precautionary Principle: A European Perspective, Human and Ecological Risk Assessment: An International Journal, 6:3, 445-458, DOI: 10.1080/10807030091124563
[106] Garnett, K. and Parsons, D.J. (2017), Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law. Risk Analysis, 37: 502-516, 516. https://doi.org/10.1111/risa.12633
[107] Peter H. Sand (2000) The Precautionary Principle: A European Perspective, Human and Ecological Risk Assessment: An International Journal, 6:3, 445-458, DOI: 10.1080/10807030091124563; Löfstedt RE. The

2.5 Summary

To summarize, the precautionary principle, in general, is applicable in cases of uncertain serious threats to the environment or human health. Even if the particulars in its various definitions might vary, all of them have a common baseline comprising of four dimensions- serious or irreversible threat, uncertainty as to its occurrence or magnitude, action to be taken by the regulatory authority in such instances and whether the principle mandates such action or provides justification for the authority choosing to take action. It is pertinent to note that uncertainty is meant to be distinct from risk and refers to either absence of information, inability to collect sufficient information or scientific divergence making it impossible to quantify the probability or magnitude or both of a threat. Even so, the uncertain threat has to be founded on some scientific knowledge.

The principle was initially presented as a higher order principle and not a brightline rule. Gradually, its incorporation into various legislations and regulations saw it take the form of a determining factor of the risk management stage of risk analysis. It started gaining support as a necessary aid for decision-making in certain circumstances of irreversible or serious threats. Furthermore, its proponents have also touted its contribution towards shaping the regulatory process itself- to make the process interdisciplinary, transparent and more cognizant of stakeholder concerns.

Within the EU, the precautionary principle has been adopted into the decision-making framework to address uncertain serious or irreversible threats to the environment and human health. The guidelines for its application help determine when and to what extent it should be relied upon. The intended goal is to help decision-making in the face of incomplete knowledge but also to make the regulatory process more cognizant of such deficiencies and inclusive of multiple disciplines and stakeholders. Currently, its operationalization takes the form of regulatory preemptory action or reversal of default assumptions as regards the safety of new activities or products.

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precautionary principle in the EU: Why a formal review is long overdue. *Risk Management*, 2014; **16**(3): 137–163; Michael D. Rogers michael.rogers@skynet.be (2011) Risk management and the record of the precautionary principle in EU case law, Journal of Risk Research, 14:4, 467-484, DOI: 10.1080/13669877.2010.547255;

Chapter 3: Criticisms Of The Precautionary Principle

3.1 Introduction

As discussed in the previous chapter, the precautionary principle has evolved to be used in different contexts and almost universally accepted as a part of decision-making frameworks. Even so simultaneously, the debate regarding its efficacy to fulfil its objectives and propensity to negatively impact regulatory processes continues. Critics of the Principle have never contested the need and importance to acknowledge uncertainty in environmental and health policy. However, it is their assertion that the Precautionary Principle does not serve this purpose.

Accordingly, this chapter elaborates on the arguments put forth by the critics of the precautionary principle in order to present a complete picture of what might be expected in practice when recourse to the precautionary principle is taken. Naturally, the potential pitfalls of applying the precautionary principle will be discussed in the context of both the intended uses of the principle discussed in the previous chapter- that of a guideline for decision-making, and as a means of shaping the regulatory process. The first section of the chapter discusses the strand of criticism that the principle, by reason of its vagueness and lack of objective markers, adds little value to the decision-making process. The second section of the chapter delves into the strand of criticism that uses public choice theory and behavioral economics to highlight the possibility of undue regulatory discretion in the implementation of the principle and the increased vulnerability to political influence it enables. This section shall, namely, elaborate upon the particular criticisms of neglecting risk/risk trade-offs, risk-aversion in the bureaucracy and regulatory overreach.

3.2 Precautionary principle as a decision-making rule

The precautionary principle has been denounced as incoherent, empty rhetoric without any instructive value and lacking scientific rigor as a decision-making rule.[108]As such, it adds no value to the existing framework of risk analysis, and perhaps may also work to make it less objective. The primary shortcoming of the principle is its vagueness. Not only does it not

[108] Bodansky, D. (1991). Law: scientific uncertainty and the precautionary principle. *Environment: Science and Policy for Sustainable Development*, *33*(7), 4-44; Chapman, P. M. (1999). Does the precautionary principle have a role in ecological risk assessment? *Human and Ecological Risk Assessment: An International Journal*, *5*(5), 885-888; Adler, J. H. (2011). The problems with precaution: A principle without principle; Charnley, G. (2000). 1999 Annual Meeting. Past President's Message: Risk Analysis under Fire. *RISK newsletter*, *20*(3).

give any instructional help to decision-makers but also increases the subjectivity of the decisions. Consequently, scientific methods get undermined. These pitfalls are briefly discussed in this section.

3.2.1 Vagueness

The crux of this criticism is that the precautionary principle is too vague to operate as a reasonable standard.[109]Opponents argue that even 30 years after its initial declaration, there is little clarity as to what it entails. Critics of the principle argue that it is lacking even if understood as a standard rather than a rule.[110] Applied logically, the principle would cannibalize itself.[111] It is redundant as guidance or a policy tool as it provides no instruction and implicitly forbids inaction, stringent regulation, and everything in between.[112]

To illustrate this point, we can consider the cholera outbreak of 1854 in London, which is oft heralded as an early instance of the successful exercise of the precautionary approach before the principle was formalized as part of environmental law. [113] The outbreak was controlled by a radical departure from the prevalent measures (which were based on the then understanding that it was an air-borne disease). This departure was the result of initial observations by Dr. John Snow, a British physician that the disease might actually be water-borne.

Here, taking regulatory action though the cause-and-effect relationship was not fully established led to savings on public health and human life. However, it could also be argued that the precautionary principle would require that any new measure not be implemented if there is uncertainty as to its adverse impacts. Thus, the same principle could lead to different outcomes and consequently, the determining factor remains the decision-maker's discretion and not guidance from the precautionary principle.

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[109] Bodansky, D. (1991). Law: scientific uncertainty and the precautionary principle. *Environment: Science and Policy for Sustainable Development*, *33*(7), 4-44; Graham, J. D., & Wiener, J. B. (2008). The precautionary principle and risk–risk trade-offs: a comment. *Journal of Risk Research*, *11*(4), 465-474.
[110] Willms, ©. (2017). Navigating Environmental Risk: When and How to Apply the Precautionary Principle.
[111] Yan, H. (2020). Refining the Precautionary Principle in Public International Law. *US-China Law Review, 17*.
[112] Sunstein, C. R. (2005). *Laws of fear: Beyond the precautionary principle* (Vol. 6). Cambridge University Press.
[113] Gee, D., MacGarvin, M., Stirling, A., Keys, J., Wynne, B., & Vaz, S. G. (2001). *Late lessons from early warnings: the precautionary principle 1896-2000*. P. Harremoës (Ed.). Luxembourg: Office for Official Publications of the European Communities.

3.2.2 Lacking scientific rigor

A major consequence of the absence of clear objective markers in the precautionary principles is the marginalizing of scientific decision-making.[114] Preferences between conflicting actions cannot be established using common agreed markers. As a result, it has a "paralyzing" effect on decision-making as every action under the principle could also be disallowed under it, because of the inherent subjectivity.[115] As it reiterates the inability to quantify or compare uncertainty, it pushes policymaking farther away from objective tests and allows perceptions rather than facts to prevail.[116] In this aspect, alternative decision-making tools, such as cost-benefit or cost-cost analysis, though incomplete, might still be better as they allow uniform and consistent scientific methods to be the basis for decisions. [117]

3.2.3 Vulnerability to political influence

The vagueness and inherent subjectivity of the precautionary principle together make the decision-making more amenable to political influence[118].Reviewing regulatory actions and their justifications is close to impossible due to the absence of objective checks and the vague range of actions justified by the principle.[119] Problems arising from such increased political influence (e.g. rent-seeking[120],regulatory capture[121]etc) have been widely discussed within the public choice literature and are not a particular phenomenon of the precautionary principle. Nevertheless, the argument remains that the precautionary principle exposes risk analysis to such issues by making it more vulnerable to political influence.[122]

3.3 Precautionary principle as a means to shape the regulatory process

In this context, the criticisms about vagueness and absence of workable rules may not be as pertinent. However, then previously mentioned concerns regarding regulatory over-reach and

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[114] Chapman, P. M. (1999). Does the precautionary principle have a role in ecological risk assessment? *Human and Ecological Risk Assessment: An International Journal*, *5*(5), 885-888,886.
[115] Sunstein, C. R. (2005). The precautionary principle as a basis for decision making. *The Economists' Voice*, *2*(2).
[116] Sanderson, H., & Petersen, S. (2002). Power analysis as a reflexive scientific tool for interpretation and implementation of the precautionary principle in the European Union. *Environmental Science and Pollution Research*, *9*(4), 221-226.
[117]Sunstein, C. R. (2005). The precautionary principle as a basis for decision making. *The Economists' Voice*, *2*(2).
[118] Sunstein, C. R. (2005). *Laws of fear: Beyond the precautionary principle* (Vol. 6). Cambridge University Press.
[119] Yan, H. (2020). Refining the Precautionary Principle in Public International Law. *US-China Law Review, 17*.
[120] Tullock, G. (1967). The welfare costs of tariffs, monopolies, and theft. *Economic inquiry*, *5*(3), 224-232.
[121] Stigler, G. (1971). The economic theory of regulation. *Bell Journal of Economics*, *2*(1), 3-21;
[122] Miller, H. I., & Conko, G. P. (2004). *The Frankenfood myth: how protest and politics threaten the biotech revolution*. Greenwood Publishing Group, p. 96.

supplanting of power in choosing risk preferences are amplified. The institutional context in a majority of the applications of the precautionary principle is public administration[123] and as such issues concerning it are necessarily linked to the legitimacy of administrative decisions.[124] This second stream of criticism of the principle pertains to how the peculiarities of the precautionary principle and the subject matter it deals with lead more easily to undesirable outcomes and perversion of motives of decision-makers, who already have greater discretionary powers in this context. The criticism employs public choice theory and behavioral biases to explain the greater likelihood of occurrence of the following:

3.3.1 Ignoring risk/risk trade-off

A very particular criticism against the Precautionary Principle is that it results in neglecting the risk/risk trade-off involved in decision-making. A precautionary response to one 'target' risk may lead to substitute risks that are even worse.[125]In addressing the potential threat posed by a new technology/product, the harm caused or worsened by not adopting it is ignored.[126]Each regulatory intervention against potential risks simultaneously generates countervailing risks because of the inherent scientific uncertainty being dealt with.[127] Such generation of countervailing risks reduces the net benefit that an intervention may achieve; in some cases, resulting in more harm than good. Critics argue that the Precautionary Principle ignores the balancing of such risks.

Sunstein (2005) provides the example of the issue of food scarcity and starvation being ignored whilst regulating the use of agricultural innovations. A similar analysis is put forth by

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[123] Yan, H. (2020). Refining the Precautionary Principle in Public International Law. *US-China Law Review, 17*.
[124] Lenaerts, K. (2004). "In the Union we trust": Trust-enhancing principles of Community law. *Common Market Law Review*, *41*(2), 317-343.
[125] Adler, J. H. (2011). The problems with precaution: A principle without principle
[126] Sunstein, C. R. (2005). *Laws of fear: Beyond the precautionary principle* (Vol. 6). Cambridge University Press., 7.
[127]Here it is relevant to note the distinction between true risk /risk trade-offs and ignoring risk superior alternatives presented in Hansen, S. F., von Krauss, M. K., & Tickner, J. A. (2008). The precautionary principle and risk-risk trade-offs. *Journal of Risk Research*, *11*(4), 423-464. They argue that risk/risk tradeoffs need not be treated as inevitable in regulatory action. Indeed, in 9 of the 33 cases analyzed by them regulatory intervention to curb a certain risk would necessarily generate a countervailing risk (true risk/risk tradeoff). However, in 13 of the cases it was that regulatory action did not consider the risk-superior alternative, or the risk superior alternative became available soon after the intervention. In these cases, it is the alternative intervention being ignored, not the countervailing risk. As such, the behavioral biases discussed in this section later would not be the same in these instances. (the remaining 11 cases had to do with false countervailing threats and thus also not true risk/risk trade-offs).

Aerni (2019)[128] explaining how the excessively precautionary classification of Genetically Modified seeds causes an obstacle in achieving EU's Sustainability Development Goals.

Behavioral economics is employed to explain why the precautionary principle would result in such a trade-off neglect. Regulations under the Principle seem more palatable and necessary because only a subset of the relevant effects is 'on-screen'. When a single problem is placed in view, it can be difficult to see the full consequences of legal interventions. In perceiving the risk, the public at large falls prey to the availability heuristic and tends to only consider the targeted harm and the possible benefits or other adverse impacts do not register.[129]

This incomplete or faulty perception of risk is further compounded by loss aversion and reliance on the benevolence of nature.[130] Loss aversion would cause a focus on potential losses and disregard for the benefits of a proposed technology thereby resulting in an incorrect speculation of the net benefit of an intervention.[131] Additionally, it has been argued that loss aversion results in unfamiliar risks occasioning more concern than familiar risks, perhaps with the same propensity for damage.[132]Thus, the evaluation of the uncertain threats under Precautionary Principle is likely to be inflated and the benefit of the threatening activity masked.

In the context of environmental threats, loss aversion is seen to be frequently accompanied by a mistaken belief that nature is essentially benign.[133] Threats to safety and health are viewed as stemming from only or mostly human intervention altering the status quo.[134] As a result, a departure from status quo suffers from the prejudicial assumption of posing undue risk.[135].This unsubstantiated belief in nature is, perhaps, further strengthened by the framing

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[128] Aerni, P. (2019). Politicizing the Precautionary Principle: why disregarding facts should not pass for farsightedness. *Frontiers in plant science*, *10*, 1053.
[129] Sunstein, C. R. (2005). *Laws of fear: Beyond the precautionary principle* (Vol. 6). Cambridge University Press,4.
[130] Sunstein, C. R. (2005). *Laws of fear: Beyond the precautionary principle* (Vol. 6). Cambridge University Press,6.
[131] Sunstein, C. R. (2005). *Laws of fear: Beyond the precautionary principle* (Vol. 6). Cambridge University Press, 7.
[132] Majone, G. (2002). The precautionary principle and its policy implications. *JCMS: Journal of Common Market Studies*, *40*(1), 89-109.
[133] Nollkaemper, A. (1996). What you risk reveals what you value, and other dilemmas encountered in the legal assaults on risks. *The Precautionary Principle and International Law: The Challenge of Implementation. Kluwer Law International, The Hague*, 73-94
[134] Applegate, J.S. (2002). The Taming of the Precautionary Principle. *William and Mary Environmental Law and Policy Review, 27*, 13.
[135] Sunstein, C. R. (2005). *Laws of fear: Beyond the precautionary principle* (Vol. 6). Cambridge University Press, 6.

of the Precautionary Principle's objective- tackling of uncertainty for threats occasioned by human activity. However, it must be noted that there does not seem to be any evidence or suggestion that such framing was done with the purpose of encouraging reliance on the benevolence of nature. It was simply to distinguish between threats from human activity and those from natural phenomena (management and prediction of such natural disasters comprises a different field of science). Even so, the framing of the principle could still contribute towards a prejudicial bias against alterations to the natural status quo.

Even though most formulations and particularly the EU's communication of the principle explicitly require a balancing of the benefits of the potentially threatening activity or product, critics maintain it to be meaningless as it would still be plagued by an over-estimation and aversion of the onscreen losses.[136]

3.3.2 Risk-averse bureaucracy

A frequently speculated adverse scenario resulting from the Precautionary principle is a technological standstill.[137] Failing to recognize threats in the realm where the Precautionary Principle operates, would result in serious repercussions and public outcry. Bureaucrats would fear being censured for a failure to initiate precautionary action more than they would for delaying approvals for new technology.[138]The fear of censure would incentivize risk-averse bureaucrats to either ban or over-regulate deviations from *status quo*. [139]

Such occurrences can be observed in regulation of medicines. Damage caused by approving bad medication is more salient and thus, steadfastly avoided. It could result in over regulation and delaying approval for a necessary medication causing as many deaths as bad medication but would not be easily attributable to the bureaucrat's decision.[140] This is clearly illustrated

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[136] Miller, H. I., & Conko, G. P. (2004). *The Frankenfood myth: how protest and politics threaten the biotech revolution*. Greenwood Publishing Group

[137] Nollkaemper, A. (1996). What you risk reveals what you value, and other dilemmas encountered in the legal assaults on risks. *The Precautionary Principle and International Law: The Challenge of Implementation. Kluwer Law International, The Hague*, 73-94; Miller, H. I., & Conko, G. P. (2004). *The Frankenfood myth: how protest and politics threaten the biotech revolution*. Greenwood Publishing Group, p. 96.

[138] Mueller, D. C. (2003). *Public choice III*. Cambridge University Press, 375-385.

[139] Mueller, D. C. (2003). *Public choice III*. Cambridge University Press, 375-385. Certain instances from bureaucracy in the United states of America are elaborated to lend credence to this theory: undue delays in drug certification by the FDA in the United States; The Department of Housing and Urban Development constituted to help "distressed cities" i.e. cities where risks in housing programs were high, was found to have allocated funds to cities with less risky investment projects to avoid the criticism that the projects were not successful; Risk-averse Veterans Administration hospital officials concentrate on providing outputs that are easily measured (hospital beds, patient days) at the cost of quality of service, an unmeasurable dimension of output.

[140] Adler, Jonathan H., "The Problems with Precaution: A Principle without Principle" (2011). Faculty Publications. 1538.https://scholarlycommons.law.case.edu/faculty_publications/1538

in the delay for approving Misoprostol, a medication preventing gastric ulcers.[141] At the time, between 10,000 and 20,000 people died of gastric ulcers per year in the United States of America. The delayed approval process, even though it was available in other parts of the world, might have cost as many as 8,000 to 15,000 lives. Thus, in seeking to prevent one risk—the risk of approving an unsafe drug—the regulatory agency contributed to the risk of gastric ulcers by preventing the use of a potentially lifesaving drug.[142]

Furthermore, requiring 'never-ending proof' of the benign nature of a permitted activity and such a reversal of the burden of proof, in turn, would increase costs of innovators and producers bringing about a technological standstill.[143]

3.3.3 Regulatory overreach

The Precautionary Principle has been heralded as a trust-enhancing instrument within the European community[144]. When faced with causal uncertainty, an individual is unable to determine how to evaluate new events.[145] Furendi[146] describes this a 'crisis of causality' – when the authority of knowledge is undermined, people are reluctant to interpret events that appear to be random incomprehensible acts. To begin with, fears in relation to such threats are possibly heightened because of the biases discussed in the section on trade-off neglect. In such a scenario, a government involving the application of precautionary principle is viewed favorably, allays the fears and increases willingness to accept regulatory interventions.

Precisely this trust-enhancing property of the precautionary principle is the cause for concern for its critics. They believe that an enhanced trust level reduces the checks on the discretion exercised by the regulator. Thus, decisions claiming to have been made in line with the Precautionary Principle are less likely to be questioned.[147] As a result, a risk of an illegitimate

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[141] Adler, Jonathan H., "The Problems with Precaution: A Principle without Principle" (2011). Faculty Publications. 1538.https://scholarlycommons.law.case.edu/faculty_publications/1538
[142] Adler, Jonathan H., "The Problems with Precaution: A Principle without Principle" (2011). Faculty Publications. 1538.https://scholarlycommons.law.case.edu/faculty_publications/1538
[143] Sunstein, C. R. (2005). *Laws of fear: Beyond the precautionary principle* (Vol. 6). Cambridge University Press, 10.
[144] Lenaerts, K. (2004). "In the Union we trust": Trust-enhancing principles of Community law. *Common Market Law Review*, *41*(2), 317-343.
[145] Furedi, F. (2007). The only thing we have to fear is the 'culture of fear'itself. *American Journal of Sociology*, *32*, 231-234.
[146] Furedi, F. (2009). Precautionary culture and the rise of possibilistic risk assessment. *Erasmus L. Rev.*, *2*, 197.
[147] Majone, G. (2002). The precautionary principle and its policy implications. *JCMS: Journal of Common Market Studies*, *40*(1), 89-109.

dominance by regulators over their citizens is raised; even when, perhaps, the goals of protecting health and safety of the citizens are not necessarily being met.[148]

The motivation to increase regulatory dominance at the level of the bureaucrat is consistent with the theory of bureaucracy in the public choice literature. Regulatory agencies would be motivated to increase scope, prestige, powers, size, and budget.[149]The precautionary principle would also allow for creation of agencies tasked with monitoring, information exchange etc. [150] resulting in expanded budgets. Simultaneously, it would lead to agencies being more vulnerable to regulatory capture because of increased familiarity with industry players as well as information shared arising from partisan entities.[151]

Applying the rationale of this criticism in the interplay of federal and local governmental institutions presents another peculiar problem. Purnhagen (2014)[152] provides an instance of how such illegitimate or excessive dominance would be a fruitful goal in federal relations. An argument is presented to show that the EU uses the Precautionary Principle as a shield to interfere in Member State's legislative powers but is not contested because of the increased trust in the EU governance, especially as the EU would be claiming to ensure greater safety of human life. Similarly, Member-states may also use the guise of precaution to establish protectionist measures or deviate from the standards established for the common market.'[153]

3.4 Conclusion

The inherent subjectivity and lack of clarity as regards the application of the precautionary principle raises concerns that apart from it not adding any value to the decision-making process, it might rather adversely affect the regulatory process resulting in an excessively

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[148] Nollkaemper, A. (1996). What you risk reveals what you value, and other dilemmas encountered in the legal assaults on risks. *The Precautionary Principle and International Law: The Challenge of Implementation. Kluwer Law International, The Hague*, 73-94.
[149] Niskanen, W. A. (1968). The peculiar economics of bureaucracy. *The American Economic Review*, *58*(2), 293-305; Butler, E. (2012). Public choice-a primer. *Institute of Economic Affairs Occasional Paper*, *147*.; *supra* Mueller, 362.
[150] Discussed under the action dimension in the previous chapter.
[151] Lofstedt, R. E. (2003). The precautionary principle: Risk, regulation and politics. *Process Safety and Environmental Protection*, *81*(1), 36-43.
[152] Purnhagen, K. (2014). The behavioural law and economics of the precautionary principle in the EU and its impact on internal market regulation. *Journal of consumer policy*, *37*(3), 453-464.
[153] ECJ. 2007. Judgment of the European Court of Justice of 13 September 2007. Land Oberösterreich and Republic of Austria v Commission of the European Communities. Appeal – Directive 2001/18/EC – Decision 2003/653/EC – Deliberate release into the environment of genetically modified organisms – Article 95(5) EC – National provisions derogating from a harmonisation measure justified by new scientific evidence and by a problem specific to one Member State – Principle of the right to be heard. Joined cases C-439/05 and C-454/05.

risk-averse regulatory regime. Whether the previously discussed added values or the presently discussed criticisms occur in the actual cases of operationalisation of the precautionary principle and to what extent remains a question for positive analysis. The following chapters of the thesis will seek to precisely determine the answer to this question in the instance of the reauthorization of glyphosates within the European Union.

Chapter 4: Role Of The Precautionary Principle In The Reauthorization Of Glyphosates In The EU

4.1 Introduction

Even as the precautionary principle is increasingly being adopted across the world, there remain concerns about its operationalization and potential to marginalize scientific decision-making.[154] The question of whether the principle actually is recognized and used in policymaking as well as judicial decisions has been explored in the literature.[155] These papers study if any significant role has been played by the principle in the formulation of rules and regulatory regimes. However, as has been recognized in the earlier chapter, concerns exist of the precautionary principle influencing decisions of bureaucrats and politicians in the day-to-day implementation of the principle as well.

In this chapter, an attempt is made to analyse whether the precautionary principle has played any role in the decision of authorizing glyphosates in the EU. The chapter can roughly be understood as structured in four parts. The first part elaborates on the basis for the precautionary principle in decision-making in relation to pesticides in general at the EU level. This overview helps understand the institutional background in which the decision in question was taken as also the status of the precautionary principle in the risk analysis procedure. An additional section in this part briefly comments on inherent complexities and difficulties of chemical risk regulation to illustrate how such regulation is more frequently prone to uncertainties and consequently amenable for the application of the precautionary principle.

The second part discusses whether the specific instance of glyphosate authorization was particularly suitable for invoking the precautionary principle. The developments in the glyphosate case, and the primary issues of conflict therein are detailed. Furthermore, an

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[154] Bodansky, D. (1991). Law: scientific uncertainty and the precautionary principle. Environment: Science and Policy for Sustainable Development, 33(7), 4-44; Chapman, P. M. (1999). Does the precautionary principle have a role in ecological risk assessment? Human and Ecological Risk Assessment: An International Journal, 5(5), 885-888; Adler, J. H. (2011). The problems with precaution: A principle without principle; Charnley, G. (2000). 1999 Annual Meeting. Past President's Message: Risk Analysis under Fire. RISK newsletter, 20(3)

[155] Heyvaert, V. (2006). Facing the consequences of the precautionary principle in European Community law. *European Law Review*, *31*(2), 185; Heyvaert, V. (2006). Guidance without constraint: assessing the impact of the precautionary principle on the European Community's chemicals policy; Stokes, E. (2008). The EC courts' contribution to refining the parameters of precaution. *Journal of Risk Research*, *11*(4), 491-507; Vlek, C. (2009). A precautionary-principled approach towards uncertain risks: review and decision-theoretic elaboration. *Erasmus L. Rev.*, *2*, 129.

attempt is made to explain the differences in opinions based on the institutional set-up, mandate and procedure of the bodies holding these differing opinions. The discussion in the second part highlights the plausible divergence in scientific opinion providing the basis for adopting a precautionary approach.

Following this positive investigation, the third part, then, analyses the resolving of the issues in the decision described in the second part to evaluate whether they are consistent with the provisions of the first part and if any regulatory response can be discernibly attributed to the precautionary principle. Furthermore, it is also assessed whether the criticisms of the precautionary principle discussed in the previous chapter are apparent in decision in the glyphosate case.

Investigating the role of the principle in this case is in furtherance of answering whether the precautionary principle does actually impact decision-making in practice. The normative implications of the result of this investigation (for instance, a reframing of the purpose /utility of the principle as a trust-enhancing instrument alone) will be discussed at a later stage in the dissertation.

The fourth part of the chapter proceeds to disentangle the EU decision into individual responses by Member-states at the EU level. To this end an explanation of competencies and possible responses, both at the EU level and within their own country, is presented. Following this, the responses and internal regulations of Member-states are compared with aim of identifying factors that may have potentially shaped individual countries' attitude towards pesticides in general (and glyphosates in particular). Additionally, it helps to classify Member-State responses and accordingly, guide the selection of countries and identification of questions for the case-studies in the following chapter.

4.2 Precautionary principle in pesticide regulation

In this section, the legal basis and appropriateness for invoking the precautionary principle for decisions relating to pesticide authorization will be discussed. To this end, the section can be understood as having two distinct sub-sections. The first one illustrates the inherently uncertain nature of risks posed by chemicals increasing the likelihood of a scientific uncertainty or plausible divergence of opinions that allows for the possibility of a precautionary approach. The second sub-section then details the provisions in the regulations governing authorizations for pesticides, detailing principles, and considerations that

regulators should bear in mind whilst making risk assessments. A particular focus is laid on explaining how these regulations allow for the use of the precautionary principle and how in certain cases the regulations necessarily require the use of the precautionary principle. In addition to giving the background for the case discussed in the chapter, this section also provides the guidelines against which the eventual decision can be compared and analysed in the latter part of the chapter.

4.2.1 Nature of risk regulation relating to chemicals

Before embarking in understanding what role, if any, was played by the precautionary principle in the particular case of glyphosates, it would be useful to understand some underlying facets of risk regulation in chemicals. The field of chemical risk analysis more frequently deals with uncertainty of impacts and political choices in relation to risks.[156]Problems occur both due to the complex science involved as well as the necessarily political choices involved in the framing and managing of risk.[157]

Undertaking research on hazards posed by chemicals is an expensive and demanding task.[158] Data can often be incomplete resulting in unclear outcomes.[159] Establishing causal links between exposure to chemicals and health or environmental effects requires multiple high-quality case studies.[160] This complexity is further compounded by the extremely diverse and varied properties of different chemicals in combination with each other.[161] Calculating or estimating the risk[162] posed by a substance, would require additional information on potential exposure levels of a substance. Uncertainty persists in the exposure assessment as well by reason of the variety and complexity of dispersion pathways and the propensity of chemicals towards bioaccumulation.[163]Additionally, uncertainties about the benign nature of a substance are raised by the worry of long latency periods[164] - hazards may remain hidden for a

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[156] L. Kramer (2016) *EU Environmental Law* 8th Ed Sweet & Maxwell, 224.
[157] Fisher, E. (2008). The 'perfect storm' of REACH: charting regulatory controversy in the age of information, sustainable development, and globalization. Journal of risk research, 11(4), 541-563, 542.
[158] Case C-419/17P Deza [2019] C: 2019:52, para 37.
[159] 2019/1 N. de Sadeleer, The PP and Management of Uncertainties in EU Law on Chemicals, published at http://desadeleer.eu., 3.
[160] *Ibid,* 3; Saracci, R. (2016). *The hazards of Hazard Identification. In Old and New Risks: Challenges for Environmental Epidemiology.*
[161] Schummer, J. (2001). Ethics of chemical synthesis. *HYLE–International Journal for Philosophy of Chemistry*, *7*(2), 103-124, 111.
[162] Risk, here, refers to the probability of the intrinsic hazard of the chemical occurring based on actual exposure to the substance in real use.
[163] Godard, O. (2012). The Precautionary Principle and chemical risks. The Philosophy of Chemistry: Practices, Methodologies, and Concepts, 65-96, 87.
[164] Cranor, C. F. (2016). *Toxic torts*. Cambridge University Press, 216.

substantial period before adverse effects being felt. By such time, path dependencies may have caused the substance to get heavily entrenched and not easy to eliminate.[165]Another peculiarity casting doubt on being able to conclusively derive results is the occasional finding that the behaviour of certain chemicals is contrary to the belief that a higher dose has more serious effects than a lower one[166]; as a result, for such chemicals it becomes impossible to establish an acceptable threshold below which disruptive effects could be considered negligible. Considering all these traits, there would be uncertainty involved in most risk assessments of chemicals, thereby making it more frequently appropriate for the application of the precautionary principle.

Within the predominantly used risk analysis framework (particularly in the EU), risk assessment and risk management are distinguished as scientific and political exercises respectively.[167]It shall be discussed later in this chapter how such a distinction is not strictly true. However, at this instance it is useful to note that the permeation of political choices in the formal, standardized, science-based objective risk assessment stage can be illustrated in the context of chemical regulations. Results of assessments depend on how the risk is framed, where an acceptable level is set, what outcomes are considered relevant to study and how the dilemmas raised in the earlier paragraph are chosen to be resolved.[168]

Apart from these considerations, academicians have cited conflicts over chemical safety as inherently controversial [169]. They give rise to debates centred not only on competing values and scientific uncertainty, but also the role and duties of an administrative state in the distribution and management of risk.[170]Questions of acceptable, legitimate, and expected

[165] Hansen, S. F., von Krauss, M. K., & Tickner, J. A. (2008). The precautionary principle and risk-risk tradeoffs. *Journal of Risk Research*, *11*(4), 423-464.
[166] A Gides and AM Soto, 'Bisphenol A: contested science, divergent safety evaluations' in EEA Report No 1/2013 (Luxembourg, 2013) 217 and 219.
[167] Fisher, E. (2013). Framing risk regulation: A critical reflection. *European Journal of Risk Regulation*, *4*(2), 125-132, 127.
[168] 2019/1 N. de Sadeleer, The PP and Management of Uncertainties in EU Law on Chemicals, published at http://desadeleer.eu, 12-15.
[169] Fisher, E. (2008). The 'perfect storm' of REACH: charting regulatory controversy in the age of information, sustainable development, and globalization. Journal of risk research, 11(4), 541-563, 453; Beck, U. (1996). Risk society and the provident state. *Risk, environment and modernity: Towards a new ecology*, *31*, 29-43.
[170] Fisher, E. C. (2007). *Risk regulation and administrative constitutionalism*. Bloomsbury Publishing.

State action and responses to uncertain threats cannot be easily disentangled from its legal and socio-political culture.[171]

4.2.2 Regulation on plant protection products (2009)

This section will elaborate on the stated objectives, rationales, and provisions of the regulation on pesticides in the EU to explain the legal setting in which the conflict about glyphosates arose and was resolved. It will elaborate the mandate and competencies the European Commission had at its disposal to resolve the issue and the status of the precautionary principle in this realm.

The 2009 Regulation on Plant Protection Products (PPP regulation)[172] establishes the rules and procedure for authorisation and placing on the market of pesticides used in agriculture, horticulture, parks, and gardens. Initially, regulations harmonizing procedures for placing hazardous substances on the market were intended to foster the functioning of the internal market.[173] Nevertheless, they have proven in recent times, handy to address environmental concerns as well.[174] The section below shall briefly summarize the provisions of the legislation to set the context for the decisions arrived at by the EU in relation to glyphosates.

- ***Subject matter***

Substances used to suppress, eradicate, and prevent organisms that are considered harmful are grouped under the term 'pesticide.'[175]The term includes both plant protection products (PPPs) used on plants in agriculture, horticulture, parks, and gardens; as well as biocides used in other applications such as disinfectants etc.[176]

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[171] Brickman, R., & Jasanoff, S. (1985). Iglen T. Controlling chemicals: the politics of regulation in Europe and the United States. Ithaca; Fisher, E. (2014). Chemicals as Regulatory Objects. *Review of European, Comparative & International Environmental Law*, *23*(2), 163-171.
[172] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
[173] De Sadeleer, N. (2014). *EU environmental law and the internal market*. OUP Oxford, 157-161, 291,304 and 358-382.
[174] 2019/1 N. de Sadeleer, The PP and Management of Uncertainties in EU Law on Chemicals, published at http://desadeleer.eu, 4.
[175] Bourguignon D., EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017, 3.
[176] Bourguignon D., EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017, 3.

Plant protection products (PPPs) refers to commercial products containing a mixture of one or more active ingredients and for one of the listed purposes in the PPP regulation.[177] Active ingredients are components that have a biological impact and serve the core function of the product.[178] Whereas the co-formulants (including a surfactant, safener or synergist) add additional attributes such as water-solubility etc. and do not exert the main biological impact intended. [179]However, they could have biological or chemical side-effects worth considering in risk-analysis and policymaking.[180] Simply put, different commercial products based on the same active ingredients could have differing impacts, based on the other ingredients or processes in which they have been combined for commercial production. E.g., glyphosate is the active ingredient of many herbicides and can be studied for its impact on human health by itself. However, the products placed on the market for use, such as Roundup Classic or Roundup Ultra (by Monsanto), have different compositions and accordingly, pose different risks. Many a times, the varying formulae for PPPs, thus, developed by corporations are likely to be kept undisclosed as proprietary knowledge.

- ***Guiding rationales of the legislation***

The aim of regulation has been recognised to be 'achieving a high level of protection of human health and environment whilst ensuring free circulation of substances in the internal market.'[181] To this end, certain underlying principles can be recognised as guiding the legislation.

a Separation of risk assessment, risk management and risk communication

In general, EU law relating to regulating hazardous substances implements the three-step process of risk analysis[182]: risk assessment, risk management and risk communication. It is built upon the division of powers in scientific and political decisions propounded in the early

[177] Regulation (EC) No 1107/2009, art. 2(1)
[178] Székács, A., & Darvas, B. (2018). Re-registration challenges of glyphosate in the European Union. *Frontiers in Environmental Science*, *6*, 78, 79.
[179] Székács, A., & Darvas, B. (2018). Re-registration challenges of glyphosate in the European Union. *Frontiers in Environmental Science*, *6*, 78, 79.
[180] Regulation (EC) No 1107/2009, Art. 25-27
[181] Regulation (EC) No 1107/2009, Art.1.
[182] 2019/1 N. de Sadeleer, The PP and Management of Uncertainties in EU Law on Chemicals, published at http://desadeleer.eu, 6.

days of research about risk analysis.[183] In this framework, the first step, risk assessment, has to be conducted by scientific experts, possibly using mathematical modelling, to arrive at probability of occurrence of harm. This involves investigating both hazard (inherent risk) and exposure.[184]Hazard refers to the inherent toxicity of a product whereas the possible exposure of such a hazardous substance in real life scenarios is considered in assessing the risk. Traditionally, it is carried out in the four stages - the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk.[185]It must be noted that the regulation lays stress on a hazard-based approach for assessing active ingredients in particular.[186]Essentially, active ingredients must be assessed on the basis of their intrinsic properties rather than on the basis of the risks they may pose. However, this preference is belied by the mandate of the EU agencies tasked with risk assessment – they are required to consult with stakeholders with a view of determining risk levels based on exposure and realistic use.[187] There is no one methodology prescribed for assessment, but rather guidelines for implementing an appropriate methodology.[188] Risk assessment is not a single, fixed method of analysis. Rather it is a systematic approach to organising and analysing scientific knowledge and information[189]. It would be particularly difficult to develop a one-size-fits-all assessment in this realm as the very nature and purpose of different pesticides differ. E.g. Some are meant to be toxic and released into the environment by reason of such toxicity (weed killers), whereas others are to be assessed on the possibility of them inadvertently becoming part of products used closely by humans (cosmetics or food).[190]

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[183] This separation of scientific and political aspects was first suggested in 'National Research Council, Risk Assessment in the Federal Government: Managing the Process, (Washington DC: National Academy Press 1983).'

[184] 2019/1 N. de Sadeleer, The PP and Management of Uncertainties in EU Law on Chemicals, published at http://desadeleer.eu, 7.

[185] Case T-451/13 Bayer [2018] T : 2018 :624, para 113. See also GFL, Art 3(11). In its Communication on the PP, the Commission defines the four components of a risk assessment: Székács, A., & Darvas, B. (2018). Re-registration challenges of glyphosate in the European Union. Frontiers in Environmental Science, 94.

[186] Bourguignon D., EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017, 13; Regulation (EC) No 1107/2009, Annex II Art. 2.

[187] European Parliament Council (2002). *Laying down the General Principles and Requirements of Food Law, establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety. 178/2002/EC Regulation. OJ L031*. Available online at: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:en:PDF

[188] Regulation (EC) No 1107/2009, 10.

[189] National Research Council, Science and Judgment in Risk Assessment, (Washington DC: National Academy Press 1994), 4.

[190] ... IPCS. (2010). *WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2009*. World Health Organization.

Following the completion of a systematic assessment in this manner, the decision about how the risk is to be managed is vested with politicians- a public process to decide how safe is safe enough[191]. For this purpose, policymakers would have to weigh the different interests involved, investigate available alternatives and costs of shifting, factor in the effectiveness of the risky substance, envisage potential monitoring needs occasioned by the approval as well as possibilities of distributing or mitigating the risk posed before deciding on the appropriate regulatory response.[192]The scientific expertise provides the decision-makers with objective data to make informed decisions but is not the sole determining factor- *the scientist's opinion is sufficient but not necessary or binding for regulatory decisions*.[193]Thus, risk management decisions are inherently subjective and discretionary.

The final step that remains is the communication of the risk in an effective manner.[194] Communication should be clear enough to translate the expertise into terms that the public understands and should be framed to help address the varying perceptions of risk.

b Precautionary principle

EU institutions and Member States must ensure consistency with the precautionary principle for all measures under the ambit of secondary law.[195]Even so, the PPP regulation makes it a point to explicitly mention adherence to the precautionary principle in its preamble as also the main body of the legislation. [196] Presumably, this salient mention of the precautionary principle is an indicator of the expectation of a strong reliance on the precautionary principle in decisions relating to PPPs.

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[191] Vermeire, T. G., & van Leeuwen, C. J. (Eds.). (2007). Risk Assessment of Chemicals: An Introduction. Springer, 7.
[192] 'Other legitimate factors' may be taken into account by the risk manager. See GFL, recital 19 and Art 3(12); Regulation (EC) 1829/2003 on GM food and feed, Art 6(6). Likewise, the GCt and the CJEU and have upheld the right to balance different factors in a number of cases (Case C-180/96 P UK v Commission [1996] ECR I-3903; Case T-199/96 Bergaderm [1998] ECR II-2805; Cases T-344 &T-345/00CEVA Santé Animale [2003], para 66). As far as WTO law is concerned, attention to 'other legitimate factors' such as taking into account the real use of the product is deemed to be admissible. (AB, EC: Measures Affecting the Prohibition of Asbestos and Asbestos Products (WT/ D135/AB/R) paras 162 and 174).
[193] Case T-13/99, Pfizer Animal Health SA v Council [2002] E.C.R. II-3305 The Court held "For instance, the Commission can depart from EFSA's scientific opinion in as much it can appropriately justify such departure."; Also, in Case C-405/92ArmandMondiet [1993] ECRI-6136, paras31-32; Case C-120/97Upjohn [1999] ECR-I-223, para47.
[194] 2019/1 N. de Sadeleer, The PP and Management of Uncertainties in EU Law on Chemicals, published at http://desadeleer.eu, 7.
[195] TFEU, Art. 34-36
[196] Regulation (EC) No 1107/2009, Art 1(4)

c *Principle of Substitution*

The principle of substitution, which is considered as stemming from the precautionary principle [197], has been enshrined separately in the PPP regulation.[198]This principle posits that the mere existence of a less hazardous alternative is adequate grounds for the prohibition of the substance in question. The European Commission is tasked with listing active ingredients deemed as 'Candidates for Substitution' that undergo comparative assessment.[199]Substitution helps the assessment of balancing interests as well as determining the proportionality of measures fragmenting the internal market.[200]

d *Mutual recognition*

Mutual recognition allows national authorities to rely on risk assessments carried out by other national authorities to grant access to the market for products. [201]Such mutual recognition is in line with the aim of the regulation to encourage harmony in the internal market. Additionally, it would serve to minimise costs of conducting burdensome assessments in relation to the marginal benefit that may arise from simultaneous, potentially duplicitous, risk assessments being conducted by each national authority. Apart from being recognised as a core principle in the preamble, the legislation also makes it salient by providing for a zonal division into three zones to facilitate authorization[202] and the possibility of applications for parallel trade permits[203]. Applications are assessed by one Rapporteur Member State for each zone and the other Member States can rely on its authorization to allow PPPs to be placed on the market. Thus, a balancing act is sought between flexibility to counter different circumstances in the Member States, maintaining free circulation in the EU market and minimizing administrative costs of risk assessment.

e *Sustainability*

The regulation acknowledges the EU's dedication to sustainable development. In particular, it aims to do so through Integrated Pest Management, wherein non-chemical methods fulfilling the purpose of pesticides are to be explored and preferred, if shown to be

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[197] Bourguignon D., Authorisation of pesticides in the EU, EPRS, European Parliamentary,2018., 3
[198] Regulation (EC) No 1107/2009, art.50.
[199] Regulation (EC) No 1107/2009, Art.24.
[200] De Sadeleer, N. (2014). EU environmental law and the internal market. OUP Oxford.
[201] Regulation (EC) No 1107/2009, Art.40.
[202] Regulation (EC) No 1107/2009, Art.40(1)(a).
[203] Regulation (EC) No 1107/2009, Art.52.

satisfactory.[204]Separate regulations exist mandating the Member States to develop and adopt plans to reduce pesticide-dependence.[205] However, such requirements have not been mentioned as considerations in the approval process within the PPP regulation.

- ***Authorisation procedure***

Pesticides are regulated by a 2-stage approval process. Authorizations for active ingredients are granted at the EU level; however, PPPs (commercial products) must seek separate authorizations from Member States to be placed on the market.[206] This dual level distinction of jurisdiction is consistent with EU principle of subsidiarity.

a Approval of active ingredients

Active ingredients are assessed at the EU level based on the hazard level of the substance (not the risk, which is dependent on exposure level).[207] The assessment must reveal the substance in question to be satisfying certain exemption criteria shown in Table 4.1 below.[208]

Table 4.1: **Principal exemption criteria for approval for active ingredients.**
(Source: European Parliamentary Research Service)

	Plant Protection substances	**Biocidal substances**
Effects on human health	Cannot be classified as carcinogenic, mutagenic, or toxic to reproduction	
	Cannot be considered an endocrine disruptor	
Effects on the environment	Cannot be considered as a persistent, bio-accumulative, and toxic (PBT) substance, or a very persistent very bio-accumulative (vPvB) substance	
	Cannot be considered a persistent organic pollutant (PoP)	

The approval process takes about 2 to 2.5 years and goes through the following stages:

- A manufacturer applies to a Rapporteur Member State[209] providing documentation including toxicological and ecotoxicological studies, along with information on residues,

[204] Bourguignon D., Authorisation of pesticides in the EU, EPRS, European Parliamentary,2018, 3.
[205] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve a sustainable use of pesticides
[206] Regulation (EC) No 1107/2009, Art.7 and Art.33
[207] Regulation (EC) No 1107/2009, Annex II
[208] Regulation (EC) No 1107/2009, Art.27
[209] In its reply to the 'Stop Glyphosate' European Citizens' Initiative, the European Commission indicated that when submitting a request for renewing an approval, the Rapporteur Member State 'is assigned by the Commission and cannot be chosen freely.(Communication from the Commission on the European Citizens'

and on the fate and behaviour in the environment of the pesticide.[210] Applications specify the intended uses, particularly the treated crops.

- A national authority competent to conduct risk assessment from the Rapporteur state verifies the admissibility of the application. Within one year, this authority undertakes and reports an initial risk assessment. The period can be extended (but within reason)[211], if additional information is required.

- The European Food Safety Authority (EFSA) opens the 'draft assessment report' from the national authority for public comment as well as inputs from industry peers and stakeholders. Initially, the EFSA would release significantly redacted documents at this stage.[212] However, 'access to documents (particularly in relation to emissions to the environment)' has been adjudged by the CJEU to be a right of the public to obtain environmental information under the Aarhus Convention.[213]After reflecting on all the viewpoints and studies presented, the EFSA gives it conclusions regarding the risk assessment of the substance to the European Commission

- The European Commission, based on this assessment, engages in risk management, and adopts a regulation. Such regulation must necessarily be endorsed by the 'Standing Committee on the Food Chain and Animal Health'(PAFF).[214]

- If approved, such approval would specify one or more permissible uses and can include additional limitations and conditions.[215] Approval is granted for a maximum period of 10

Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", December 2017 available at : https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_eci_final.pdf)

[210] For plant protection products, the information that has to be included is listed in Commission Implementing Regulation (EU) No 283/2013

[211] Regulation (EC) No 1107/2009, Art 9, Art.17

[212] Regulation (EC) No 1107/2009, Art 16 stipulating the public disclosure of the application dossier and draft assessment report allows for the redaction of any information that has been requested to be treated as confidential.

[213] Judgments of 23 November 2016 relating to cases C-442/14 (Bijenstichting / Bayer, points 95-96) and C-673/13 P (Commission v Greenpeace Netherlands and PAN Europe, points 79-81).The Court ruled that the use of a plant protection product or biocidal product equated to 'emissions into the environment', a subject about which the general public has the right to obtain information (including data on the composition and quantity of pesticides used, the date and place of use, and information on the environmental impact of these emissions).

[214] For more detail on the procedures in question, see A. Hardacre and M. Kaeding, Delegated and Implementing Acts: EIPA Essential guide, 2013, p. 9.

[215] Plant protection substances: The list of approved active substances is published in Commission Implementing Regulation (EU) No 540/2011. The list is also accessible via the register of approved active substances on the European Commission website.

years; however, it can be reviewed at any point. Derogations in relation to the applicable period are also permitted in certain situations.[216]

b Product Authorisation

Products to be placed on the market are authorized at the Member State level. In addition to their active ingredients having approval from the EU, the product has to be shown to be sufficiently effective in realistic conditions of use, to not have any harmful effects, either directly or indirectly, on humans or animals and it does not have any unacceptable impact on the environment.[217]

As mentioned earlier, assessment of whether such criteria are met can be conducted by one Member State and relied upon by others or can be based on the zonal system. [218] Furthermore, speedier authorisation processes are provided for in case of low-risk ingredients[219] or intended minor uses of the product.[220]

Authorised products continue to be regulated with special provisions regarding packaging, labelling, and advertising. Member States are obliged by law to make monitoring and control arrangements, and some involved parties must maintain a register.[221]

However, it must be noted, that the findings of a 2017 Overview Report on Audits of Authorization systems in the EU Member States[222] indicate that the Member States, on average, do not benefit from the support provided by measures for mutual recognition. They continue to maintain specific national requirements and are discordant with respect to evaluation methodology. An unintended, and undesirable, consequence of the resultant delays

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[216] Regulation (EC) No 1107/2009, sub-section 4 (Section 1, Chapter II)
[217] Bourguignon D., EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017, 16.
[218]If the Member States belong to two different zones, the authorization granted by recognition cannot be used to gain recognition in a third Member State.
[219] Regulation (EC) No 1107/2009, Art.47. (In particular, the product's active substances must have been approved as low-risk substances, the product may not contain any substances of concern)
[220] Authorisation for a product in a Member State may be extended to less widely grown crops (known as 'minor uses').
[221] For plant protection products, professionals in the sector must retain records on the quantities produced, distributed, imported, and exported for a period of five years, whilst professional users must retain records of the products used for three years.
[222] Overview report on a series of audits carried out in EU Member States in 2016 and 2017 in order to evaluate the systems in place for the authorization of plant protection products, Directorate-General for Health and Food Safety, July 2017, available at: https://ec.europa.eu/food/audits-analysis/overview_reports/act_getPDF.cfm?PDF_ID=1021

in processing requests is a higher number of emergency authorisations[223]- temporary authorisations without a full evaluation being performed.

- ***Persisting issues***

The legislation attempts to provide a balanced and harmonized framework for pesticide regulation. Even so, certain challenges and dilemmas remain to be addressed.

a Costs

Regulatory costs for regulating pesticides are not negligible- risk assessment and monitoring of compliance both require extensive data collection and consequently represent a noteworthy expense. Approximately, the total cost of legislation on chemical products for the agrochemical sector is estimated at 12.8 % of value added (or 2.6 % of turnover), i.e. €388 million per year.[224] Studies by the agrochemical industry estimate that developing a new active substance and placing a new product on the market takes 11 years on average; the average expenditure necessary for the research and development of a new plant protection product is in the range of $286 million.[225] Research and development of products, beyond entrepreneurial reasons, is necessitated by reduction in the number of effective plant protection products due to quickening emergence of resistance to existing products.[226]

b Conflicts of interest and bias in approval procedure

The European Ombudsman has considered and observed that the European Commission may have been too lenient in its practices in approving active ingredients and may not have been taking the precautionary principle sufficiently into account.[227]One of the possible reasons for this occurrence, is a failure to address 'revolving door situations' within the working of the

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[223] PAN Europe, Client Earth and Bee Life, Bee Emergency Call, 2017. Member States issued 1 100 emergency plant protection product authorizations that did not meet the criteria (authorized for a period of 120 days to contend with a 'danger which cannot be contained by any other reasonable means'). The report states that a large number of these authorizations do not provide information on the nature or impact of the 'danger', or the 'other reasonable means' that could be used.
[224] Maroulis, N. et al., Cumulative Cost Assessment for the EU Chemical Industry, European Commission, 2016, p. 104 and p. 130. That estimate is an average for the period from 2004 to 2014
[225] Phillips McDougall, The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010 to 2014. R&D expenditure in 2014 and expectations for 2019, 2016, pp.3-4.
[226] Bailey, A. et al., Biopesticides: Pest Management and Regulation, CABI, Wallingford, 2010.
[227] European Ombudsman, Decision, case 12/2013/MDC, 18.02.2016

EFSA and ECHA.[228] There is more than one instance of conflicts of interests casting doubts on the Agencies' decisions.[229]

c *Cumulative risks*

Studies suggest that the combined effect of residues of plant protection products may be significantly higher than the sum of the effects of each residue taken separately.[230]These cumulative effects are not considered either in the approval procedure nor in the EFSA's annual reports on pesticide residues.[231]

4.3 Suitability for using the precautionary principle in the reauthorization decision for glyphosate.

The earlier section highlighted the guidelines for assessing risks posed by pesticides, the possibility of reliance on the precautionary principle in risk regulation of pesticides and the higher likelihood of scenarios warranting such reliance in case of purposefully toxic chemical products like pesticides. This section will focus specifically on the decision relating to glyphosates and how the previously discussed guidelines and procedures played out in the case of analysing the risk posed by glyphosates.

The section begins with a brief history of glyphosates, its uses and relevance in the global market with a view of establishing the practical significance of a decision to regulate it. Following this description, a timeline of major events in its authorisation process is laid out. These events help identify the primary contentious issues in the debate surrounding glyphosates. It is sought to understand the reasons for divergence of scientific opinions in the case, including gaps in communication of regulatory decisions. Identification of the basis of

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[228] European Court of Auditors, Management of conflict of interest in selected EU Agencies, Special Report No 15/2012, 11.10.2012. The four agencies audited were the European Aviation Safety Agency, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority. The report identified ECHA as having 'significant shortcomings' and EFSA as having 'shortcomings'

[229] For e.g., European Parliament decision of 10 May 2012 on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2010, 2011/2226(DEC). The Chair of the EFSA Management Board resigned from her post on 9 May 2012 (see EFSA, press release, 9.5.2012).

[230] Member States issued 1 100 emergency plant protection product authorizations that did not meet the criteria (authorized for a period of 120 days to contend with a 'danger which cannot be contained by any other reasonable means'). The report states that a large number of these authorizations do not provide information on the nature or impact of the 'danger', or the 'other reasonable means' that could be used.

[231] EFSA, EFSA presents cumulative assessment group methodology for pesticides, press release, 12.07.2013. In 2016, specific software was developed to manage cumulative risk assessment (EFSA, Pesticides: breakthrough on cumulative risk assessment, press release, 27.01.2016).

divergence in risk assessments will help elucidate if uncertainty exists as to the extent as to warrant the exercise of precaution.

4.3.1 Re-authorization of glyphosates as an active ingredient in the EU

- ***An introduction to glyphosates***

Glyphosate was introduced as an active ingredient in herbicides in 1971 and since then has remained the leading herbicide active ingredient in global markets[232]- currently representing 12% of the global pesticide market.[233] Initially, it enjoyed patent protection, which was renewed based on novel composition (combining with particular co-formulants). In 1991, glyphosate became a generic compound in most parts of the world outside the United States. Eventually, even the US patent of glyphosates expired in 2000.[234]

The primary purpose of glyphosates is to combat weeds that compete with cultivated crops or present problems for other reasons (e.g. on railway tracks). Typical use involves applications before sowing to control weeds. Such use facilitates better growth of crops by eliminating competing plants.[235] Complementarily, it leads to a lessened requirement of ploughing machines, which has a beneficial impact of reducing soil erosion and carbon emissions. To a lesser extent as a pre-harvest treatment to facilitate better harvesting by regulating plant growth and ripening as well as post-harvest desiccation.[236]

Data indicates that the worldwide market for this ingredient is continuously increasing. The period between 1990 and 2005 witnessed a 44% annual growth and since 2005, sales have maintained an 8% annual growth till 2014.[237] This tremendous growth post 1990 can be

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[232] Dill, G. M., Sammons, R. D., Feng, P. C. C., Kohn, F., Kretzmer, K., Mehrsheikh, A., et al. (2010). "Glyphosate: discovery, development, applications, and properties," in Glyphosate Resistance in Crops and Weeds: History, Development, and Management. ed V. K. Nandula (Hoboken, NJ: Wiley), 1–33.
[233] Transparency Market Research (2014). Glyphosate Market for Genetically Modified and Conventional Crops - Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2013–2019. Albany: Transparency Market Research Available from: http://www.transparencymarketresearch.com/glyphosate-market.html
[234] Székács, A., & Darvas, B. (2018). Re-registration challenges of glyphosate in the European Union. Frontiers in Environmental Science, 78.
[235] Transparency Market Research (2014). Glyphosate Market for Genetically Modified and Conventional Crops - Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2013–2019. Albany: Transparency Market Research Available from: http://www.transparencymarketresearch.com/glyphosate-market.html
[236] European Commission, Glyphosates- facts and status.
https://ec.europa.eu/food/plant/pesticides/glyphosate_en
Accessed 01.03.2020
[237] Benbrook, C. M. (2016). Trends in glyphosate herbicide use in the United States and globally. *Environ. Sci. Eur.* 28:3. doi: 10.1186/s12302-016-0070-0; Bonny, S. (2011). Herbicide-tolerant transgenic soybean over 15 years of cultivation: pesticide use, weed resistance, and some economic issues. Case of the USA. *Sustainability* 3, 1302–1322.

attributed to the introduction of glyphosate-tolerant (GT) crops and expansion of the use of multiple trait genetically modified (GM) crops.[238] However, it must be noted that use of glyphosates also increased in regions without such GT/ GM crop cultivation.[239] This would be an indication that glyphosates were being used for other purposes such as pre-harvest desiccation, combating weeds in horticulture or other open spaces etc.[240] It is pertinent to note this development as it elucidates various channels of exposure to the ingredient, outside of being actively engaged in agriculture.

The dominant player in the glyphosate market has been the Monsanto Corporation with its glyphosate-based herbicides under the Roundup group. The market has been very favourable for Monsanto owing to the patent protection enjoyed by glyphosates for about three decades.[241]Roundup has also managed to counter the dropping of sales after the expiration of the patent. Introduction of GT crops enabled the presentation of Roundup as exclusively linked to use with GT crops (or Roundup Ready crops).[242] Consequently, farmers choosing to cultivate GT crops feel the necessity of using glyphosates, or specifically Roundup as the preferred pest-management technique.

- ***Timeline of glyphosate authorisation in the EU***

Glyphosates were first evaluated in 1995 and were registered under the then existing EU registration system of PPPs.[243] The authorization granted then, expired in 2012- by which time Regulation 1107/2002(present PPP regulation) was already in force. Accordingly, a

[238] Benbrook, C. M. (2016). Trends in glyphosate herbicide use in the United States and globally. *Environ. Sci. Eur.* 28:3. doi: 10.1186/s12302-016-0070-0; Bonny, S. (2011). Herbicide-tolerant transgenic soybean over 15 years of cultivation: pesticide use, weed resistance, and some economic issues. Case of the USA. *Sustainability* 3, 1302–1322.
[239] Transparency Market Research (2016). Global Glyphosate Market to Reach US$8.79 bn by 2019 Propelled by Increasing Adoption of Genetically Modified Crops. Albany: Transparency Market Research Available from: http://www.transparencymarketresearch.com/pressrelease/glyphosate-market.html
[240]Berger, G., Graef, F., Pallet, B., Hoffmann, J., Brühl, C. A., and Wagner, N. (2018). How does changing pesticide usage over time affect migrating amphibians: a case study on the use of glyphosate-based herbicides in German agriculture over 20 years. *Front. Environ. Sci.* 6:6.
[241] Székács, A., & Darvas, B. (2018). Re-registration challenges of glyphosate in the European Union. Frontiers in Environmental Science, 78.
[242] Transparency Market Research (2014). Glyphosate Market for Genetically Modified and Conventional Crops - Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2013–2019. Albany: Transparency Market Research Available from: http://www.transparencymarketresearch.com/glyphosate-market.html
[243] European Commission (1991). *Council Directive 91/414/EEC of 15 July 1991 Concerning the Placing of Plant Protection Products on the Market. OJ L230:1–32.*

renewal of the authorization of glyphosates under the new regulatory regime was ordered. [244] However, the process of re-registration of glyphosates as well as 38 other active ingredients was postponed until 2015 citing reasons of delays caused by overburdening of the pesticide authorization renewal process.[245] The approval for the substances was extended for the intervening period while the assessment was carried out.

This unexpected postponement was not welcomed by the public at large; neither was the reason cited for it accepted easily.[246] Consequently, it led to a heightened interest on part of the public in the re-registration process of glyphosates. Simultaneously, the number of published studies on the effects of glyphosates also increased exponentially.[247]As a result, the issue of glyphosate authorization has become a highly contentious issue within the EU in the past five years. A brief timeline of the events[248] leading up to its eventual authorization will help highlight the primary aspects of the conflict.

- In 2010, the application for renewal of authorization was submitted by a consortium of manufacturers called Glyphosate Task Force to the Rapporteur Member State Germany. The German Federal Institute for Risk Assessment (BfR) produced its 'draft assessment report' in December 2013. Amongst other things, the report concluded that glyphosate was not carcinogenic.[249]
- The EFSA started the peer-review process and stakeholder consultations in January 2014. This entailed consulting additional national institutes, experts as well as eliciting additional information from the Glyphosate Task force.

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[244] European Commission (2011b). *Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L153:1–186*.
[245] European Commission (2010). *Commission Directive 2010/77/EU of 10 November 2010 amending Council Directive 91/414/EEC as Regards the Expiry Dates for Inclusion in Annex I of Certain Active Substances. OJ L293:48–57.*
[246] Székács, A., & Darvas, B. (2018). Re-registration challenges of glyphosate in the European Union. Frontiers in Environmental Science, 81.
[247] Zyoud, S. H., Waring, W. S., Al-Jabi, S. W., and Sweileh, W. M. (2017). Global research production in glyphosate intoxication from 1978 to 2015: a bibliometric analysis. *Hum. Exp. Toxicol.* 36, 997–1006.
[248] Timeline has been put together based on reporting in Bourginon (2017) (Supra 45); European Commission website (Supra 83); Communication on the Commission's response to the Stop Glyphosate Citizen's Initiative (Supra 57).
[249] German Federal Institute for Risk Assessment (2013). Renewal Assessment Report (RAR) on the Active Substance Glyphosate Prepared by the Rapporteur Member State Germany in the Framework of Regulation (EU) *No 1141/2010*.

- In March 2015, the International Agency for Research on Cancer (IARC), a body of the World Health Organisation published a report about glyphosates in the usual course of its working. The report concluded that glyphosates were *probably carcinogenic to humans*.[250] The European Commission mandated the consideration of these findings in the undergoing risk assessment by the BfR and EFSA. Additional time was allowed for the risk assessment. The approval was glyphosates was extended further till June 2016 whilst the risk assessment could be finalized

- In November 2015, the EFSA concluded its risk assessment and asserted that glyphosate is *'unlikely to pose a carcinogenic hazard to humans'.* Additionally, it raised concerns regarding some of the most commonly used substances in combination with glyphosate, specifically POE-tallowamine.[251]

- Based on these conclusions, the European Commission proposed to renew the approval of glyphosate for 15 years in February 2016. But the proposal failed to garner support from the Standing Committee on PAFF and could not be passed. The approval granted for the interim period was then further extended to allow the European Chemicals Agency (ECHA) to assess the potential carcinogenicity for the purposes of harmonized classification and labelling.[252]However, limitations on use of glyphosates were also instituted: the use of POE-tallowamine alongside glyphosate was banned. In March 2017, the ECHA classified glyphosate as not a carcinogen.

In the subsequent months, attempts were made by the European Commission to receive endorsement for a proposal of renewing glyphosate approval for 10 years. Throughout 2017, several discussion rounds, proposal revisions and votes occurred.

Meanwhile, in October 2017, the Stop Glyphosate European Citizen's Initiative submitted a request for improvements in EU pesticide use and approval process, specifically focussing on a ban of glyphosate.[253] The Initiative had collected over a million signatures supporting these

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[250] International Agency for Research on Cancer (2015). *Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos. Glyphosate Lyon: IARC. 1–92*.
[251] European Food Safety Authority (2015a). Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. *EFSA J.* 13:4302; European Food Safety Authority (2015c). Request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine. *EFSA J.* 13:4303.
[252] European Chemicals Agency (2017a). *Glyphosate Not Classified as a Carcinogen by ECHA. ECHA/PR/17/06. Mar 15, 2017*.
[253] Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", December 2017 available at: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_.

requests. In the same month, the European Parliament also weighed in with recommendations of limited approval (in relation to uses as well as period), preference for non-chemical alternatives and suggested phasing out glyphosate by December 2022. [254]

Finally, the Commission was able to garner the required majority vote in an Appeal Committee in November 2017 for the approval of glyphosates for five years.[255]

The status of glyphosate in the EU after this reauthorisation stood as[256]:

- It was approved as an active ingredient in herbicide use till 15 December 2022.
- Minimisation of glyphosate-based PPPs in public areas was suggested.
- Member States were advised to pay particular attention in the assessment of glyphosate-based PPPs to protection of operators and amateur users, vulnerability of groundwater sources, risk to diversity and non-target plants and terrestrial animals and ensuring compliance with good agricultural practices.
- Glyphosate-based PPPs cannot contain POE-tallowamine as a co-formulant.

Seemingly, the Commission's decision has been found unsatisfactory by all quarters involved. The Glyphosate Task Force (manufacturers) were unhappy with short duration of the renewal and lamented that politics, rather than science permeated the approval process. They exhorted Member States to follow scientific evidence in assessing glyphosate-based PPPs. In a similar vein, COPA-COGECA (farmers and agricultural cooperatives) were also disappointed by the derogation of the approval period to 5 years.[257] Additionally, they highlighted the importance of glyphosate in current agricultural practices and expressed scepticism about possible minimization of use and future bans. It was claimed existing technical alternatives would be inadequate in case of a glyphosate ban.[258] It would generate extra costs to institute the shifts and put food supplies at risk.[259]

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[254] Bourguignon D., EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017, 8.
[255] European Commission (2011a). *Commission Implementing Regulation Renewing the Approval of the Active Substance Glyphosate In Accordance With Regulation (Ec) No 1107/2009 of the European Parliament and of the Council Concerning The Placing of Plant Protection Products on the Market and Amending The Annex to Implementing Regulation (Eu) No 540.*
[256] Ibid.
[257] Bourguignon D., Authorisation of pesticides in the EU, EPRS, European Parliamentary,2018, 8.
[258] Reboud X. et al, 2017. Usages et alternatives au glyphosate dans l'agriculture française. Rapport Inra à la saisine Ref TR507024, 85 pages.
[259] Ibid.

On the other hand, the Pesticide Action Network and the European Citizen's Initiative were dismayed by the approval.[260] They expressed concern that bans on specific uses (such as in public areas or by non-professionals), that would not have resulted in significant countervailing cost were not instituted. Furthermore, they believed that the process of authorization revealed the need for greater transparency in the approval process- as regards the scientific evidence being used, its source funding as also positions taken by Member States in the comitology procedure.

Six Member States (Belgium, France, Greece, Luxembourg, Malta and Slovenia) reiterated to the European Commission the need for qualifications to the approval for curtailing associated risks and a sincere undertaking of a phase -out plan for glyphosates (which would include support measures for farmers).[261]Of these six countries , Belgium , France and Greece are also some of the very few countries who have set high-level measurable targets for risk-reduction and use reduction of pesticides in general.[262]

4.3.2 Divergence of scientific opinions

The timeline above reveals that the primary issue of contention was the divergence in the assessment of carcinogenicity by the IARC and the EFSA, both agencies of considerable repute and possessing scientific expertise. The IARC's finding was considered crucial by most scholars, as probable carcinogenicity would constitute a failure to meet the exemption criteria for approval. Accordingly, this section delves deeper to understand the divergence in the results of the two risk assessments. At this point, it would be useful to have some insight as to the working of the IARC to discern its affiliations, objectives, methodology, motivations to undertake a specific research and overall aim of the studies. Considering the concerns raised as regards transparency, the mandate and composition of the EFSA has also been presented to enable a comparison of structure as well as procedure between the two bodies.

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[260] Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", December 2017 available at: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_.
[261] Bourguignon D., Authorisation of pesticides in the EU, EPRS, European Parliamentary,2018, 8.
[262] European Commision Press Memo, 'Questions & Answers: Commission replies to European Citizens' Initiative on Glyphosate and announces more transparency in scientific assessments', 12 December 2017 available at: https://ec.europa.eu/commission/presscorner/detail/en/MEMO_17_5192

- ***International Agency for Research on Cancer (IARC)***

The International Agency for Research on Cancer (IARC) is the specialized cancer agency of the World Health Organization[263]. It engages in interdisciplinary research bringing together skills in epidemiology, laboratory sciences, and biostatistics with the objective of identifying the causes of cancer to facilitate adoption of preventive measures[264]. With a membership of 29 countries[265] and personnel members from almost 60 countries[266], the IARC plays an important role in coordinating international cancer research and describing the burden of cancer worldwide. These extensive operations are primarily funded by statutory contributions from its member countries[267]; but also through voluntary contributions made by donors from various sectors including government agencies, international organizations, non-governmental organizations, foundations, and charity organizations[268]. Donations from private individuals are credited to the Agency's Undesignated Contributions account to be allocated to different projects and programs based on the agency's annual budget[269].

One of the IARC's long-running publications is the IARC Monographs Programme. It identifies chemicals, drugs, mixtures, occupational exposures, lifestyles and personal habits, and physical and biological agents that cause cancer in humans.[270] Since 1971, it has evaluated 1000 agents. Monographs are prepared by ad hoc Working Groups of international scientists over a period of 12 months followed by an eight-day meeting. The Working Group is expected to evaluate all publicly available scientific information on the substance in question. For this purpose, it would include all peer- reviewed scientific publications;

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[263] IARC Statute, Rules and Regulations - Fourteenth Edition, 2014 (modified Article 7.3 of IARC Financial Regulations and updated list of Participating States as at 15 May 2024) https://governance.iarc.who.int/documentation/statute-iarc.pdf
[264] IARC Statute, Rules and Regulations - Fourteenth Edition, 2014 (modified Article 7.3 of IARC Financial Regulations and updated list of Participating States as at 15 May 2024) https://governance.iarc.who.int/documentation/statute-iarc.pdf
[265] Federal Republic of Germany, France, Italy, the United Kingdom, the United States of America, Australia, Austria, Belgium, Brazil, Canada, China, Denmark, Egypt, Finland, Hungary, India, Iran (Islamic Republic of), Ireland, Japan, Morocco, Norway, the Netherlands, Qatar, Republic of Korea, Russian Federation, Saudi Arabia, Spain, Sweden, and Switzerland. *Membership*. (n.d.). https://www.iarc.who.int/about-iarc-membership, Last accessed 19 October 2024.
[266] *IARC personnel*. (n.d.). https://www.iarc.who.int/about-iarc-staff, Last accessed 19 October 2024.
[267] World Health Organization. (2003). Financial regulations and financial rules. World Health Organization. https://iris.who.int/handle/10665/68539, Regulation VI – Assessed Contributions.
[268] World Health Organization. (2003). Financial regulations and financial rules. World Health Organization. https://iris.who.int/handle/10665/68539, Regulation VIII – Revenue: Other Sources
[269] World Health Organization. (2003). Financial regulations and financial rules. World Health Organization. https://iris.who.int/handle/10665/68539, Regulation VIII – Revenue: Other Sources
[270] IARC. *Preamble to the IARC Monographs*. 2006. http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf

however, consultations with stakeholders or appraisal of their inputs and opinions does not constitute part of the evaluation. Through a transparent process, detailing the affiliations of all scientists involved in every study assessed, the Working Group decides on the degree to which scientific evidence supports the substance's potential to cause or not cause cancer in humans. Such conclusion is not accompanied by any suggested regulatory response. The analysis of the IARC Working Group can be characterized as hazard-based: it identifies the potential threat posed by a substance without delving into the level of risk it may present in practical terms.[271]

As part of the above described Monograph Programme, the IARC published Monograph 112 in 2015 evaluating carcinogenic hazards for four insecticides and the herbicide glyphosate.[272] Conclusions were primarily based on 14 high-quality case-control studies, and 5 cohort studies particularly valuable for determining the carcinogenicity of an agent because their design facilitates exposure assessment and reduces potential for biases.[273] Impact of glyphosates was considered not just in isolation but in conjunction with the commonly used co-formulants and surfactants.[274]

The IARC uses three levels of evidence for human cancer data.[275] *Sufficient evidence* means 'that a causal relationship has been established.' However, legitimate public concerns arise already when 'causality is credible' or there is *limited evidence of carcinogenicity.* The WG, comprising of 17 expert scientists, concluded that there is *limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in animals as regards glyphosates.* In sum, glyphosates were classified into Group 2A – "probably carcinogenic to humans".[276]

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[271] Székács, A., & Darvas, B. (2018). Re-registration challenges of glyphosate in the European Union. Frontiers in Environmental Science, 91.
[272] International Agency for Research on Cancer (2015). Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos. Glyphosate Lyon: IARC. 1–92.
[273] Portier, C. J., Armstrong, B. K., Baguley, B. C., Baur, X., Belyaev, I., Bellé, R., ... & Budnik, L. T. (2016). Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA). *J Epidemiol Community Health*, *70*(8), 741-745, 742
[274] International Agency for Research on Cancer (2015). Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos. Glyphosate Lyon: IARC. 1–92.
[275] IARC. Preamble to the IARC Monographs. 2006. http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf.
[276] International Agency for Research on Cancer (2015). Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos. Glyphosate Lyon: IARC. 1–92., conclusion.

- ***European Food Safety Authority (EFSA)***

The European Food Safety Authority (EFSA) was established in response to food crises of the 1990s and early 2000s with the objective of providing high-quality independent scientific advice to European risk-managers [277]. The Founding Regulation of the agency identifies scientific excellence, transparency, independence, and openness as the key principles for the operations of the agency. The Authority's revenues consist of contributions from the European Community and from any State with which the Community has concluded agreements; as also charges for publications, conferences, training, and similar activities provided by the Authority[278]. Most of EFSA's work is undertaken in response to requests for scientific advice from the European Commission, the European Parliament, and EU Member States. However, it also undertakes the responsibility of assessment and peer review of findings for active ingredients in pesticides. Scientific advice is mostly provided by its Scientific Panels and Scientific Committee, members of which are appointed through an open selection procedure.

The Panel on Plant Protection Products and their Residues (PPR) provides scientific advice on the risk assessment of pesticides for operators, workers, consumers, and the environment. The Panel develops and reviews guidance documents on the risk assessment of pesticides. This work supports the evaluation of active substances used in pesticides, which is carried out by Rapporteur Member States and peer reviewed by EFSA staff.

Even as the EFSA stresses independence, it also admits that the pool of experts it draws from is likely to have worked with the industries it assesses at some stage of their career.[279] Concerns regarding 'revolving door 'employment between industry and regulators have also been highlighted by different auditors and the European Ombudsman.[280] To address this concern, the EFSA actively pursued developing independence policies and procedures-

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[277] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, *OJ L 31, 1.2.2002, p. 1–24.*
[278] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, *OJ L 31, 1.2.2002, p. 1–24.* Article 43.
[279] EFSA (European Food Safety Authority), 2018. EFSA rules on competing interest Management, 2018.
[280] European Court of Auditors, Management of conflict of interest in selected EU Agencies, Special Report No 15/2012, 11.10.2012.

beginning with publication of declaration of interests, reviewing decisions in which members found to have a conflict of interest were involved[281].

In 2019, a regulation aiming at greater transparency and independence within the EFSA was passed and will enter into force from April 2021 onwards.[282] In addition to the measures mentioned already, the regulation introduces further requirements to ensure transparency and strengthen robust and independent assessments. Pursuant to the regulation, the public will have automatic access to all studies and information submitted in support of any request addressed to the EFSA, early on in the risk assessment process.[283] EFSA will be notified of all studies, when these are commissioned, with a view to a future application procedure, during the pre-submission phase. This will guarantee that companies applying for authorisations submit all relevant information and do not hold back unfavourable studies. A comprehensive set of "cooling-off" rules were introduced: external experts will be automatically barred from joining EFSA's scientific panels or working groups if in the preceding two years they have been employed by, acted as consultants to, or have offered scientific advice to organisations that work in areas covered by EFSA's remit. The cooling-off periods also apply to experts who have received research funding (exceeding 25% of the total funding for the research) from such organisations. A requirement that experts declare the proportion of their annual earnings received from any organisation, body, or company whose activities fall within EFSA's areas of work has been introduced. This information will be published and used as part of the conflict-of-interest assessment. Though the regulation is a welcome measure, it must be noted that these measures were not formalized during the period of deliberations on glyphosate assessment and were considered as part of good practices.[284]

- ***Understanding the divergence in assessment***

It is relevant to consider an overall comparison of the carcinogenicity assessments of pesticides conducted by EFSA and IARC as shown in Table 4.2. This comparison does not

[281] EFSA (European Food Safety Authority), 2018. EFSA rules on competing interest Management, 2018.
[282] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance.)
[283] Regulation (EU) 2019/1381
[284] Policy on Independence and Scientific Decision-Making Processes of EFSA, adopted by the Management Board on 15 December 2011

indicate any discernible tendency of the IARC's assessments concluding higher probabilities of carcinogenicity than the EFSA.[285] Thus, the divergence in case of glyphosates cannot be satisfactorily explained in this manner.

Table 4.2: Overall comparison of carcinogenicity assessments of pesticides conducted by IARC and EFSA
(Source: Tarazano et al, 2017)
Details of classification schemes provided in the appendix

	Number of pesticides conclusively assessed as carcinogens. (Category 1A/ Group1)	Number of pesticides declared as probably carcinogenic. (Category 1B/ Group2A)	Number of pesticides suspected to have carcinogenic potential/ be possibly carcinogenic. (Category 2/ Group 2B)	Number of pesticides where it was found Insufficient data to classify as carcinogenic. (No classification/ Group 3)	Number of pesticides classified as probably not carcinogenic for humans. (No category in EU classification/ Group 4)	Number of pesticides either not assessed/no data regarding assessment published
EU	0	17	53	30	NA	4
IARC	3	8	13	34	0	56
The EU classification uses the nomenclature Category 1A, Category1B, Category 2 and No Classification. The IARC classification uses the nomenclature Group1, Group2A, Group2B, Group3 and Group 4.						

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The divergence between the two assessments can primarily be understood under the three heads of – evidence and information sources, subject of study and the aim of the assessment.[286]

[285] Category1A and Group 1 represent pesticides assessed conclusively as carcinogens. Category 2 and Group 2B have been declared to be probably carcinogenic. No classification and Group 3 and 4 refer to those pesticides where insufficient or inconclusive evidence of carcinogenicity was found.

[286] Tarazona, J. V., Tiramani, M., Reich, H., Pfeil, R., Istace, F., & Crivellente, F. (2017). Glyphosate toxicity and carcinogenicity: a review of the scientific basis of the European Union assessment and its differences with IARC. *Archives of toxicology*, *91*(8), 2723-2743.

Table 4.3: Divergences in risk assessment methodology of the IARC and EFSA

Head for Divergence	IARC	EFSA
Source of Evidence	Reliance only on highly qualified experts, published academic papers in scientific journals, published data from regulators	Also includes non-public data from industry documentations, submitted opinions of stakeholders in consultation
Subject of study	Active ingredient glyphosate as well as effects of commercial formulations of the product of practical importance[287]	Only the active ingredient glyphosate in its pure form
Aim	Hazard-based analysis; the first step used by authorities in risk assessment. Aim is to identify possibility of inherent hazard. No regulatory suggestion intended	Risk-based analysis; covering hazard identification, hazard characterisation, exposure assessment and risk characterisation. Identified hazards are not dismissed but rather the likelihood of their actual occurrence in realistic scenarios is addressed.

Focusing on the difference in the aim of the assessments, it appears that the divergence in assessments is not a significant conflict; rather the IARC represents the initial stage of a more complete assessment by the EFSA. This is evidenced also by the fact that the EFSA assessment had to necessarily consider the IARC report and the studies it relied on. When this notion is considered in combination with the fact that the IARC studies largely study the commercial formulation and cannot adequately delink the observed impacts of glyphosate and the co-formulants, the EFSA does not seem to be a greatly divergent conclusion. Glyphosate, intrinsically, do not seem to pose a threat large enough to justify the upheaval

[287] Most academic published studies study the effect of the product in the market as they do not have easy access to the pure form or specific formulations like the industry. *Portier, C. J., Armstrong, B. K., Baguley, B. C., Baur, X., Belyaev, I., Bellé, R., ... & Budnik, L. T. (2016). Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food f*, 744.

costs of replacing them. The probable effects of co-formulants that have been detected in the IARC findings can still be addressed whilst regulating the placing of PPPs on the market.

However, this more nuanced understanding of the EFSA's conclusion opens another channel of concern. The finding of "*unlikely to pose a carcinogenic hazard*" is based on choices made as to the acceptable level of risk and estimations of exposure and residue.[288] It is necessary to acknowledge the subjective nature of these choices when relying on a risk assessment based on these choices. If there is uncertainty as regards exposure, residue levels and channels of dispersion, it would be appropriate to make it salient to the policymaker. [289]

Another consequence to be aware of is the change in the toxicological profile of the assessed substance. The toxicological profile has the details of toxic potency and acceptable levels of dietary doses, exposure, and residue. The toxicological profile sets the baselines on which risk assessment is to be conducted.[290] It is, then, obvious, that extreme care must be exercised to avoid a circularity of reasoning in reassessing the toxicological profile based on the conclusions of this assessment.[291]

Apart from uncertainty resulting from apparently conflicting scientific opinions, the divergence between IARC and EFSA highlighted the need for greater transparency in the EU pesticide regulatory framework. Scientists attempting to analyse the divergence remarked on the comparative inability to evaluate the EFSA conclusions due to an over-reliance on non-publicly available industry-provided data.[292] Inadequate explanations were given for dismissing certain experimental and published studies and less weight being attached to most of the studies reviewed by the IARC. Though the assessment report was made available publicly, most citations were redacted and a list of authors and contributors to the document

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[288] Tarazona, J. V., Tiramani, M., Reich, H., Pfeil, R., Istace, F., & Crivellente, F. (2017). Glyphosate toxicity and carcinogenicity: a review of the scientific basis of the European Union assessment and its differences with IARC. *Archives of toxicology*, *91*(8), 2735.
[289] Székács, A., & Darvas, B. (2018). Re-registration challenges of glyphosate in the European Union. Frontiers in Environmental Science, 94-100.
[290] Tarazona, J. V., Tiramani, M., Reich, H., Pfeil, R., Istace, F., & Crivellente, F. (2017). Glyphosate toxicity and carcinogenicity: a review of the scientific basis of the European Union assessment and its differences with IARC. *Archives of toxicology*, *91*(8), 2735.
[291] Tarazona, J. V., Tiramani, M., Reich, H., Pfeil, R., Istace, F., & Crivellente, F. (2017). Glyphosate toxicity and carcinogenicity: a review of the scientific basis of the European Union assessment and its differences with IARC. *Archives of toxicology*, *91*(8), 2735.
[292] Portier, C. J., Armstrong, B. K., Baguley, B. C., Baur, X., Belyaev, I., Bellé, R., ... & Budnik, L. T. (2016). Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food f.

was not included. This impedes the ability to evaluate the findings of the report and raises concerns about conflicts of interest arising from sources of funding, author affiliations etc.[293]

4.3.3 Suitability for invoking the precautionary principle

The precautionary principle aims to tackle scientific uncertainty in relation to threats to the environment or human health, caused by human activity.[294] It is to be triggered, ideally, when the risk associated with an activity is not estimable – either by reason of uncertainty relating to the likelihood of the damage occurring, or to the propensity of damage, or both.[295] The discussion in section 2 illustrated the reasons for scientific uncertainty in almost all cases of risk analysis of chemicals. However, this case becomes even more appropriate for the application of the precautionary principle as uncertainty can be evidenced in the conflicting scientific opinions about the threat posed by glyphosates. Though the comparison in the previous sub-section does explain the divergence, such an explanation is conditional on there being either certainty about the underlying assumptions of exposure, residue, and dispersion as also acceptable risk levels or the uncertainty being presented to the risk managers. The concerns about transparency and inability to access the source materials heightens the doubt as to these conditions having been met. As such, the uncertainty as to possible negative impacts of glyphosates caused by divergent credible scientific opinion cannot be dispelled – making it a case suitable for the application of a precautionary approach by risk managers.

4.4 Assessing the role of the precautionary principle in the glyphosate decision

Having understood the regulatory framework and procedure in practice and the particular conflicts arising in the case of regulating glyphosates, the decision about glyphosates was seen as suitable for the application of the precautionary principle. It remains to be seen if the decision taken can be understood as determined by the precautionary principle, either as relating to the decision taken or to the regulatory process followed. This section shall seek to answer that very question- what role, if any has been played by the precautionary principle in

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[293] Foucart, S., and Horel, S. (2018). Food safety: risk of glyphosate flagged. *Nature* 555,443. Concern has been expressed regarding the expertise used by the regulatory agencies to evaluate the safety of glyphosate and point out that toxicologists at Monsanto Corp. anticipated the carcinogenicity classification of glyphosate by IARC

[294] Science for Environment Policy (2017) The Precautionary Principle: decision making under uncertainty. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol, 16.
Available at: http://ec.europa.eu/science-environment-policy.

[295] Von Schomberg, R. (2012) The precautionary principle: Its use within hard and soft law. European Journal of Risk Regulation. 2: 147–156.

the re-authorization of glyphosates as an active ingredient of pesticides in the EU? Furthermore, the case will be discussed with the aim of discerning if any of the criticisms attributed to the precautionary principle can be seen to have occurred. Finally, the question of whether the derogations from usual practice can be explained as additions of the precautionary principle will be addressed.

4.4.1 Precautionary principle as a decision-making rule

The variety of definitions of the precautionary principle make it difficult to determine the operationalization of the principle.[296]In this analysis, the four dimensions of the principle [297] (threat, uncertainty, action and command) elaborated in the previous chapter will be conceptualized in the context of the authorization process of active ingredients in pesticides and to determine what would be the outcome of the authorization process if the precautionary principle had been applied.[298] Comparing the decision of the European Commission with this ideal decision rule shall reveal to what extent the decision embodies the precautionary principle.

The threat dimension refers to 'an undesired possible state of the world'.[299] In the context of active ingredients, this can be understood as the exemption criteria that active ingredients must be shown to fulfill. Uncertainty relates to the lack of knowledge about the threat and how plausible a threat must be to trigger precaution.[300] Uncertainty in the authorization process can be understood as when there is insufficient or inconclusive research about the potential toxicity of a substance, or assessments of toxicity are weakened due to uncertain estimation of exposure level, or if there are divergent scientific opinions. The action dimension requires a regulatory response to the adverse effects.[301] In this instance, it would be the refusal to grant approval to the substance in question. Finally, the command dimension

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[296] *Supra* 1*;* See Chapter 2 of this thesis for full discussion of different definitions of the precautionary principle.
[297] Sandin, P. (1999). Dimensions of the precautionary principle. *Human and Ecological Risk Assessment: An International Journal*, *5*(5), 889-907.
[298] A similar approach can be seen in Klika, C. (2015). Risk and the Precautionary Principle in the Implementation of REACH: The Inclusion of Substances of Very High Concern in the Candidate List. *European Journal of Risk Regulation*, *6*(1), 111-120; Eckley, Noelle and Selin, Henrik, "All talk, little action: precaution and European chemicals regulation", 11 *Journal of European Public Policy* (2004), pp. 78.
[299] Sandin, P. (1999). Dimensions of the precautionary principle. *Human and Ecological Risk Assessment: An International Journal*, *5*(5), See also chapter 2 of this dissertation.
[300] Sandin, P. (1999). Dimensions of the precautionary principle. *Human and Ecological Risk Assessment: An International Journal*, *5*(5), See also chapter 2 of this dissertation.
[301] Sandin, P. (1999). Dimensions of the precautionary principle. *Human and Ecological Risk Assessment: An International Journal*, *5*(5), See also chapter 2 of this dissertation.

refers to the legal status of the action.[302] As the authorization procedure distinguishes between the risk assessment and management aspects and doesn't make scientific opinion binding, seemingly, there are no mandatory prescriptions of action. However, if it can be shown that the guidelines of risk analysis have been followed by the European Commission, their decision can be considered as justified based on the available knowledge.[303] Thus, the precautionary principle would yield an ideal-type decision rule as follows: *If there is insufficient, uncertain or divergent information about the carcinogenicity, genotoxicity, potency as an endocrine disruptor, or bio-accumulative tendencies of an active ingredient in pesticides, the European Commission is justified in refusing to grant approval to the substance.*

Bearing this ideal-type decision rule in mind, in the instant case the European Commission would have been justified in refusing approval to glyphosates. The fact that it did not do so suggests *prima facie* that the guidance of the precautionary principle as a decision-making tool was not incorporated in the Commission's decision. Admittedly, the Commission was not obligated to refuse approval. Thus, it is possible that the precautionary principle was taken into consideration and in spite of the justification the principle provided for refusal, the Commission thought it fit to grant approval. However, there is no mention of such consideration or discussion in any of the Commission's communications or reports of the various voting rounds. Consequently, the *prima facie* notion of the minimal role played by the precautionary principle, at least with regard to its use as a decision-making tool, appears to be correct.

4.4.2 Precautionary principle as a regulatory process

The interpretation of the precautionary principle as a regulatory process was explained in chapter 2 as "*the precautionary principle represents greater recognition of uncertainty, ambiguity, and ignorance……. which are usually denied and concealed…. …. it could be argued that when implemented within a broader interpretation of incertitude, the precautionary principle serves as a way to support democratic and transparent risk-related*

[302] Sandin, P. (1999). Dimensions of the precautionary principle. *Human and Ecological Risk Assessment: An International Journal*, *5*(5), See also chapter 2 of this dissertation.
[303] 2019/1 N. de Sadeleer, The PP and Management of Uncertainties in EU Law on Chemicals, published at http://desadeleer.eu, 19.

policies, in which a wide range of disciplines and stakeholders are equally welcomed to participate in the policy making process."[304]

Viewed through this lens, the regulatory regime established by the PPP regulation embodies the precautionary principle as far as the requirements of stakeholder and public consultations, periodic appraisals of authorizations as well as the acknowledgement of incompleteness of scientific knowledge are involved. Seemingly, the recognition of the precautionary principle as an underlying rationale has manifested itself in these measures. However, it must be noted that most risk regulatory frameworks incorporating risk assessment/risk management separation tend to include equivalent measures as part of the risk management stage. [305]Consequently, it is debatable whether these measures are additional features fostered by the precautionary principle or would have been a part of the legislation as part of the traditional EU risk regulatory framework in any case.

A major shortcoming of EU pesticide regulation, highlighted at different parts in this chapter, has been the lack of transparency. Perhaps, then the endeavor to increase transparency in the decision-making process and reducing reliance on industry-produced documentation might be viewed as the value addition of the precautionary principle. The measures introduced do not do away with the requirement of reporting for the industry, but rather caution against such reports as the only source of data for risk assessments. Moreover, these reports are not the same as public disclosure. These industry-produced reports were being fed to the regulatory agency as data for decision-making and not being opened to the public at large or even other stakeholders associated with plant protection products. As such, even if the information asymmetry is being addressed, the requirement of reporting would not impact management decisions of information-disclosers in the same manner as when the disclosure is to the public.[306]In fact, the new measures require that these reports become more accessible to all stakeholders. This requirement aligns with the stakeholder centric approach being suggested for sustainability reporting by behavioral law and economics.[307]

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[304] Wibisana, M. R. A. G... "Law and economic analysis of the precautionary principle." Desertasi Doktor Maastricht University, Maastricht (2008).
[305] See discussion on risk management in section 2.2 of this chapter.
[306] Fung, A., Graham, M., Weil, D., & Fagotto, E. (2004). The Political Economy of Transparency: What makes disclosure policies effective?
[307] Darbellay, A. (2023). A behavioural law and economics approach to sustainability information. Law and Financial Markets Review, 17(1), 4–15.

However, these measure for more effective transparency systems are an outcome of the Better Regulation Agenda of the EU and not the precautionary principle. But, again, increased transparency has been called for facilitating improved and rigorous scientific reviews of findings in line with good scientific practices.[308] It would also be necessitated by the Better Regulation Agenda of the EU.[309] Access to documents as a right under the Aarhus Convention has also been extended to studies about pesticides by the CJEU.[310] Thus, addressing concerns of transparency neither requires the endorsement of the precautionary principle, nor do they seem to be emanating from its guidance.

The authorization process in the glyphosate decision does not exhibit any significant deviation from the procedure laid out within the regulation, suggesting a minimal influence of the precautionary principle. The major difference in the regulatory process was the extended time period for reaching a decision- this may be viewed as a consequence of including greater participation and addressing multiple risk perceptions along the lines of the precautionary principle. However, this argument is weakened by the fact that the approval for glyphosates was never suspended, even temporarily throughout the protracted process. Allowing for the sale and use of glyphosates whilst a decision about its acceptable toxicity is reached would not be consistent with a precautionary approach.[311]

4.4.3 Criticisms of the precautionary principle

Having assessed that the precautionary principle has played a minimal role in influencing the glyphosate decision, it would be, nevertheless, interesting to further analyze if any of the criticisms of the precautionary principle discussed in the earlier chapter can be observed as having occurred.

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[308] Portier, C. J., Armstrong, B. K., Baguley, B. C., Baur, X., Belyaev, I., Bellé, R., ... & Budnik, L. T. (2016). Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food f, 745.

[309] European Commission, Completing the Better Regulation Agenda: Better solutions for better results (2017), available at : https://ec.europa.eu/info/publications/completing-better-regulation-agenda-2017_en

[310] Judgments of 23 November 2016 relating to cases C-442/14 (Bijenstichting / Bayer, points 95-96) and C-673/13 P (Commission v Greenpeace Netherlands and PAN Europe, points 79-81).The Court ruled that the use of a plant protection product or biocidal product equated to 'emissions into the environment', a subject about which the general public has the right to obtain information (including data on the composition and quantity of pesticides used, the date and place of use, and information on the environmental impact of these emissions).

[311] Case T-13/99Pfizer, above, para199

- ***Risk/risk trade-off***

The precautionary principle garners criticism that it would lead to neglecting risk-risk tradeoffs. In addressing the potential threat posed by a technology/product, the harm caused or worsened by not adopting it is ignored.[312]

In this instance, the EFSA has made specific reference to opinions of farmers and agricultural studies as to changes in yields that would be caused by reduction or ban of glyphosates as also the ease and costs of shifting to alternative existing technology.[313]It must be noted that such considerations are not essential for assessing the inherent hazardous nature of active ingredients and would be better included whilst determining the authorization of PPPs.[314] Nevertheless, the inclusion of such concerns indicates that the decision-makers did not lose focus of the risk-risk trade-off involved in the decision.

- ***Risk-averse bureaucracy***

A frequently speculated adverse scenario resulting from the Precautionary principle is a technological standstill.[315] Failing to recognize threats in the realm where the Precautionary Principle operates would result in serious repercussions and public outcry. Bureaucrats would fear being censured for a failure to initiate precautionary action more than they would for delaying approvals for technology.[316]

The public outcry in the instant case is evidenced by the widespread support of the 'Stop Glyphosates European Citizen's Initiative. Here, it is also interesting to note that European decision-makers had seen the experience in the United States: where the Environmental

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[312] See chapter 3 for a full discussion; Sunstein, C. R. (2005). Laws of fear: Beyond the precautionary principle (Vol. 6). Cambridge University Press.
[313] See section 4.3.2 'timeline of authorization'
[314] *It is an interesting consideration that the risk/risk trade-off viewed as per the criterion of reversibility as understood in ecological economics would result in a similar outcome as upon application of the precautionary principle.*
[315] See chapter 3; Nollkaemper, A. (1996). What you risk reveals what you value, and other dilemmas encountered in the legal assaults on risks. The Precautionary Principle and International Law: The Challenge of Implementation. Kluwer Law International, The Hague, 73-94; Miller, H. I., & Conko, G. P. (2004). The Frankenfood myth: how protest and politics threaten the biotech revolution. Greenwood Publishing Group, p. 96.
[316] *Mueller, D. C. (2003). Public choice III. Cambridge University Press*, 375-385. Certain instances from bureaucracy in the United states of America are elaborated to lend credence to this theory: undue delays in drug certification by the FDA in the United States; The Department of Housing and Urban Development constituted to help "distressed cities" i.e. cities where risks in housing programs were high, was found to have allocated funds to cities with less risky investment projects to avoid the criticism that the projects were not successful; Risk-averse Veterans Administration hospital officials concentrate on providing outputs that are easily measured (hospital beds, patient days) at the cost of quality of service, an unmeasurable dimension of output.

Protection Agency had declared glyphosates as non-carcinogenic[317] but the Californian Supreme Court had awarded large compensation to operators using glyphosates that had developed non-Hodgkin's lymphoma.[318] This contradictory judicial decision had caused severe harm to the credibility of the EPA and public opinion to turn against the bureaucrats. Considering the observable public opposition in the EU to glyphosates and the unsavory experience in the United States, a plausible scenario could have been the Commission banning glyphosates simply bowing to public pressure. Thus, it would seem that the precautionary principle has not acted to enhance risk – aversion in the bureaucracy (even if so amongst the general populace). It must also be borne in mind that interest groups with greater political power might have acted against the public pressure behind the scenes. However, it would still mean that the precautionary principle did not play a role in the manipulation of the bureaucracy or to combat the pressure from any such possible interest group.

- ***Regulatory over-reach***

Critics regard the capacity of the precautionary principle as a trust-enhancing instrument[319] as being potentially detrimental to regulatory accountability. The perception that regulatory interventions are aimed at protecting humans from catastrophic harm increases the trust placed by the public in regulators and might lead to an unquestioning acceptance of the exercise of excessive regulatory responses.[320]

The limitations accompanying the authorization of glyphosates could be viewed as additional regulatory interventions, albeit within the competencies granted by the legislation. However, the only enforceable intervention is the ban on complementary use of glyphosate and POE-tallowamine, a combination having been shown to have significant adverse impacts conclusively by numerous studies.[321] The other qualifications are recommendatory in nature and make no attempt to supersede on Member State's abilities to regulate PPPs. Recommendations regarding minimizing use are in line with European pesticide policy

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[317] United States Environmental Protection Agency (2015). *Evaluation of the Carcinogenic Potential of Glyphosate. Washington DC p. 1–87*. Available online at: https://www.acsh.org/wp-content/uploads/2016/05/EPA-glyphosate-document-final.pdf
[318] Pilliod et al. v. Monsanto Company (Case No. RG17862702, JCCP No. 4953).
[319] Lenaerts, K. (2004). "In the Union we trust": Trust-enhancing principles of Community law. Common Market Law Review, 41(2), 317-343.
[320] See chapter 3 for a full discussion.
[321] Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", December 2017 available at: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_.

formulated under the Sustainability Directive and do not seek to justify themselves as being precautionary measures. In sum, there has been no overreach beyond the already granted regulatory competencies.

- ***Derogation in relation to approval period***

The discussion in the section elucidates that the precautionary principle seems to have played a very minimal role in the authorization of glyphosates. However, a major derogation could possibly be attributed to the precautionary approach. The approval was granted for a period of 5 years, rather than the usual renewal interval of 10 years.

The legislation does allow for derogations from the prescribed maximum. However, such derogations are envisaged for cases of substances being assessed as not meeting the approval criteria but still being approved, as their immediate absence would pose a 'grave danger to plant life.'[322] What can be viewed as a temporary authorization in these cases is intended as a stopgap till satisfactory alternatives to tackle the 'grave dangers' can be developed. Nowhere in the decision of the Commission, its communications thereafter and responses to the Citizen 's Initiative has there been any statement indicating that the glyphosate authorization is a temporary and consequently, shorter authorization of this kind.

Thus, the deviation from usual practice would be understood rightly as a precautionary compromise in a case of scientific uncertainty. Considering the high regulatory costs involved in the authorization process, shortening the period of approval would have a noteworthy impact. But it must be noted that the EU Commission did not begin by suggesting a shorter approval period; it was reached upon through discussions with Member States in a bid to secure the mandatory endorsement from the PAFF committee. Thus, the Commission's inherent risk management decision shows minimal influence of the precautionary principle. However, the concessions made to the original decision suggest that Member State's preferences could indeed be shaped by the principle. The next step in the dissertation would be investigating whether the precautionary principle played a role in the risk analysis of glyphosates by Member States- while endorsing or rejecting the decision at the EU level as well as in the authorization of glyphosate-based PPPs at the Member State level.

[322] Regulation (EC) No 1107/2009, sub-section 4 (Section 1, Chapter II).

4.4.4 Conclusion

The analysis in this chapter suggests that though precaution permeates the risk analysis framework in pesticide regulation, in the case of glyphosates, divergent scientific opinions did not naturally lead to the adoption of a more cautious or risk-averse regulatory response. The regulations allowed for the application of the precautionary principle. Additionally, it has also been shown that it would have been an appropriate case to rely on it. However, despite these conditions, the precautionary principle appears to have played at best a minimal role in the decision-making. Thus, this decision raises the relevant question of whether bureaucrats are actually incorporating the principle in case-specific decision making. If the answer to this question is found to be negative, it would imply that the intended value addition of the precautionary principle is not being achieved. At the same time, the analysis shows that the criticisms levelled against the principle have also not transpired in this instance. Consequently, considering the precautionary principle seems to not have an impact either way, an important consideration for future research might be the reframing of the aim and operation of the precautionary principle.

4.5 Response of individual member states at the EU level

In the previous sections, the research was focused on the EU decision to renew authorization for glyphosates. Studying the timeline of the decision presented in the previous section suggests that the Commission originally had determined to renew the authorization for the maximum possible period of 10 years. The reduction in the renewal period seems to be a political compromise to secure the approval of the required number of Member States. As a result, it is relevant to study the reasoning of Member States as regards their decision and whether the precautionary principle has played a role in it.

In this section, the individual responses of Member-States at the EU level will be discussed. To this end, firstly the over-arching procedure common to all EU Member States under the PPPs regulation for authorization of market access for PPPs is explained. Having thus understood the possible actions, the responses of the Member-states at the EU level are compared and classified. This section helps to further elucidate possible motivations of Member- States and factors that may influence the response to glyphosate. Additionally, this section also works as a bridge to the case-studies in the following chapters, guiding the identification of appropriate questions as also country selections.

4.5.1 Authorization for putting Plant Protection Products on the market

This section elaborates upon the procedures for assessing and authorizing plant protection products and the competencies of the regulatory body for pesticides in the EU. The previous section discussed the 2-stage authorization of pesticides under Regulation no. 1107/2009 governing authorization of plant protection products (PPPs).[323]

Authorization of an active ingredient at the EU level by itself does not grant market access for the active ingredients. Neither are they, generally, placed on the market in their pure form.[324] PPPs (also referred to as 'pesticides') in the form in which they are supplied to the user, consist of, or contain active substances, safeners or synergists,[325] These additional ingredients generally provide extra attributes to differentiate products, such as greater absorption or faster action. Each market formulation has to specify an intended use and apply for market access for that specific use separately to each EU Member State.[326] The European Commission has set up a zonal system to help harmonize the application process and reduce the duplication of efforts.[327]The authorization procedure differs based on the kind of application submitted. At this point, this section shall briefly describe the different possible kinds of applications as also the information requirements for determining whether to authorize a particular market formulation.

- ***Kinds of authorization procedures***

a First authorization of a PPP

The primary type of authorization is termed ‘first authorization of a PPP.’ As the name suggests, it refers to when the first application for market access is made in any given zone. Details governing the first authorization procedure are contained in Articles 28-39 of Regulation (EU) 1107/2009. An application is made to the EU country/countries where the Plant Protection Product is intended to be placed on the market. A zonal Rapporteur Member

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[323] European Parliament Council (2002). *Laying down the General Principles and Requirements of Food Law, establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety. 178/2002/EC Regulation. OJ L031*.
[324] Bourguignon D., EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017, 3.
[325] Székács, A., & Darvas, B. (2018). Re-registration challenges of glyphosate in the European Union. Frontiers in Environmental Science, 6, 78, 79.
[326] Bourguignon D., EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017, 7.
[327] Bourguignon D., EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017, 7.Ibid.

State (zRMS) is selected for each zone where the PPP shall be authorised (some uses are assessed by a single Member States on behalf of all zones[328]). The zRMS then proceeds with an assessment of the application; it is possible for other Member States in the same zone to comment on the zRMS's evaluation. A decision is reached by the Zonal RMS on whether to grant or refuse an authorisation. Accordingly, other Member States decide to grant or refuse an authorisation on this assessment. The duration for processing applications of first authorization should not exceed 1 year.

b Mutual recognition authorization

Mutual recognition detailed under articles 40-42 of Regulation 1107/2009 allows for the holder of an existing authorisation to apply for authorisation of the same PPP with the same use(s) and under comparable agricultural conditions. Applications for Mutual Recognition can only be made if there is an existing authorisation for the PPP in another Member State. The original authorizing state has to consent to such an application. The introduction state (Member State in which the product is sought to be introduced) has 3 months to consider the evaluation of the original State, the current scientific knowledge, and the introduction state's specific geographic and agricultural conditions to decide on the application. Refusal to grant authorization has to be accompanied with scientific or technical justifications.

c Parallel trade permits

Provisions for parallel trade permit applications are laid under article 38. Parallel trade permits allow a product that is authorised in one Member State (origin MS) to be introduced into another Member State (introduction MS) if the Member State of introduction determines that an identical product is already authorised in its territory. A simplified procedure allows this to occur within 45 days. This provision has been identified as facilitating the free circulation of PPPs in EU internal markets.

- ***Requirements for authorization and determination of authorization[329]***

An application for authorization to place a PPP on the market has to be accompanied with the evaluation of the active ingredient by the EU Commission as well as additional studies as to

[328] These uses are when the product is exclusively intended for greenhouse treatment or treatments of empty storage spaces.
[329] Reg no. 1107/2009, Article 29-32.

the absence of toxicity and the efficacy for the intended use of the particular formulation. Explanations as to why the models or tests adopted for these studies are the most appropriate also have to be provided. Additionally, information about safe application procedures, dosage, waiting periods between dosing and necessary complementary safety equipment has to be provided. Importantly, the applicant also has to submit how such safety information would be communicated to the eventual consumer, indicate the ease of obtaining suggested safety equipment and a draft label that would be affixed to the product on sale. The authority undertaking the assessment has to provide an opportunity for the applicant to submit any additional information that the authority deems missing as well as an opportunity to explain why it would not be possible to provide the requested information if that is the case.

The assessing authority has to, in the first instance, consider if the product is compliant with stipulations for the active ingredient made by the EU Commission. Secondly, it needs to be checked if any of the co-formulants have been assessed as hazardous individually or in combination with the active ingredient. Having established these basic criteria, further attention should be paid to the absence of toxic effects on human health based on realistic use scenarios within the Member State, efficacy for intended use and efficacy of the suggested safety measures.

The granting of the authorization is not a binary choice. Authorization can be granted while making stipulations about dosage, waiting periods between dosing, additional safety equipment and other risk mitigation measures. If the authorization is rejected, the justification also has to indicate why the possible risk cannot be mitigated by such measures. Provisions have to be made for appealing any decision at the national courts.

4.5.2 Member state response to glyphosates at the EU level

Having understood the possible range of responses available to a Member State, this sub-section proceeds with a preliminary overview of the various responses to glyphosate as an active ingredient and glyphosate-based products. The collective EU decision to renew the authorization for glyphosates is sought to be disentangled and understood as decisions of individual countries with differing circumstances. Furthermore, the sub-section presents a means of classifying similar response patterns together and recognizes possible commonalities explaining the response whilst also making note of deviations. Firstly, the vote to renew glyphosate authorization at the EU level will be sought to be understood in relation to the nature of agricultural holdings in individual countries. Following which, the discussion

will expand to include internal measures relating to glyphosates, if any, within the countries and use these measures as a basis to group the responses.

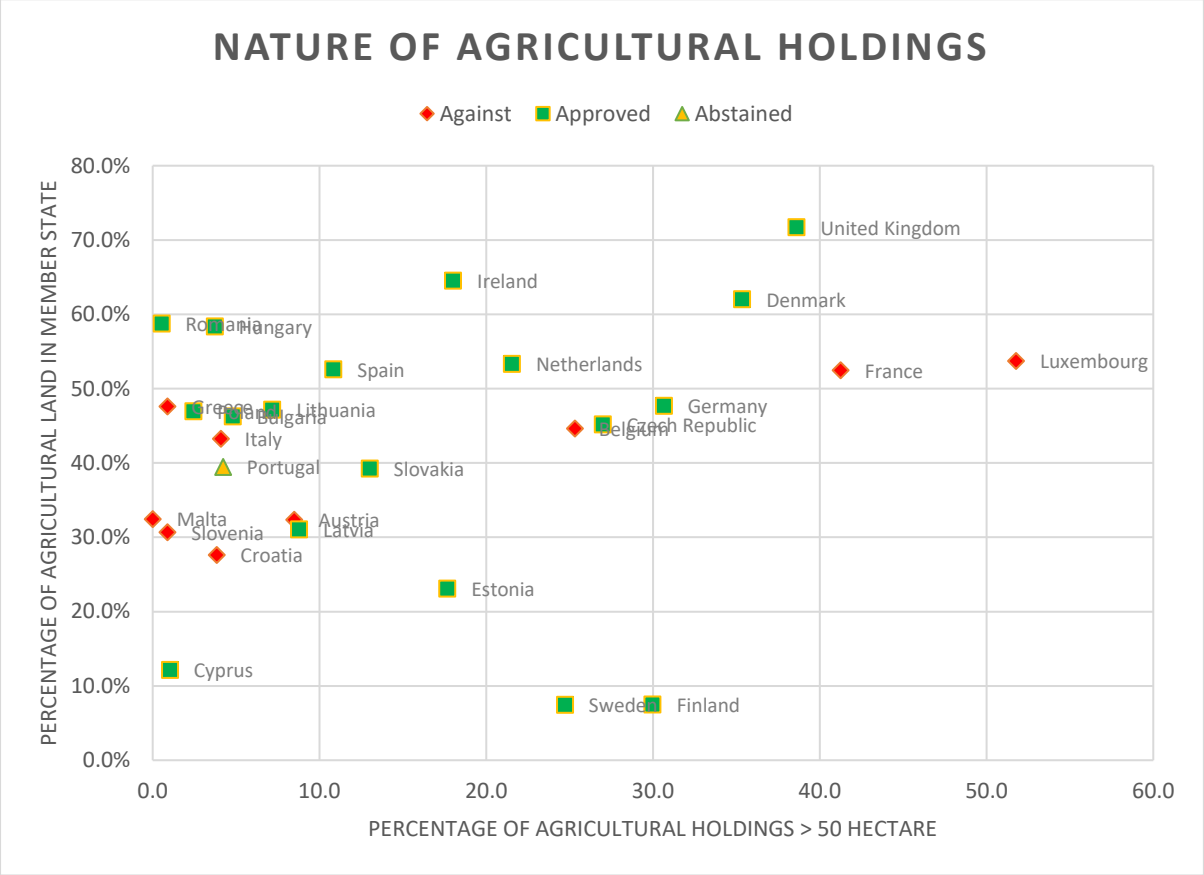
- ***Agricultural holdings and glyphosate vote***

Reliance on glyphosate-based pesticides accrues greater benefits for large-scale/ 'industrial' agriculture[330]; such agriculture is marked by larger contiguous agricultural holdings, machine-based farming, use of chemical fertilizers and pesticides and perhaps enhanced seeds.[331] Pesticides allow for efficiency in weed-removal for large land holdings. On the other hand, the comparative benefit for smaller land holdings may not be worth the investment to obtain pesticides, possible licences for its use as well as safety equipment. As such, countries, firstly with a greater share of agricultural land, and secondly with large agricultural holdings would be bigger consumers of glyphosate-based pesticides. On the one hand, there would be a greater demand for its continued use. On the other hand, it may be speculated that these countries would also be those more concerned about possible threats posed by glyphosates. However, the graph in Figure 4.1 reveals that there does not seem to be any discernible distinguishing factor relating to agricultural land, either way, amongst those who opposed the renewal of glyphosates at the EU level.

[330] E. Bozzini, Pesticide Policy and Politics in the European Union: Regulatory Assessment, Implementation and Enforcement (Palgrave Macmillan, 2017), 2.
[331] E. Bozzini, Pesticide Policy and Politics in the European Union: Regulatory Assessment, Implementation and Enforcement (Palgrave Macmillan, 2017), 2.

Fig 4.1: Share of agricultural land in total territory of country and percentage of holdings greater than 50 hectares within that land for EU member states

Source: Graph based on data from Eurostat and Euro observer[332]



The graph shows that France and Luxembourg indeed seem to be consistent with argument that a greater share of large agricultural holdings would lead to greater concern about glyphosates. However, the same logic does not follow for the other Member States that voted against the renewal of the authorization. These other states have very little or almost no large-scale agricultural holdings. On the other hand, countries like the United Kingdom with a substantial share of large agricultural holdings or even Ireland or Netherlands, who have significant agricultural land in their territory (though perhaps not as many large holdings) have approved the renewal. It is presently unclear how salient the potential threat of glyphosate was made to the public at large. This comparison is only of governmental attitudes towards the threat, knowing that a larger populace of their constituents may be at risk. Based

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[332] For Fig 4.1, Share of agricultural land, breakdown of size of agricultural holdings from: Eurostat (online data code: ef_m_farmleg), http://appsso.eurostat.ec.europa.eu/nui/, accessed 20th February 2021.
Voting by Member States: Christina Tati, EU Observer, https://euobserver.com/environment/140042, 27th November 2017, accessed 31st January 2021.

on the comparison, it would seem that a greater possibility of exposure does not affect the attitude towards the threat. Another point to bear in mind is that this conclusion does not consider any alliances based on motivations unrelated to the issue at hand that Member-States may act on whilst voting on that particular issue. Thus, Member-States may have seemingly voted to approve glyphosates even if sceptical of their safety, knowing they could institute different regulatory measures internally.

- ***The three approaches to glyphosates by Member-States***

Even if countries have approved the authorization of glyphosates as an active ingredient, it does not necessarily mean that there are no cautionary measures against glyphosates at all. It may so happen that a country has approved the authorization considering the threat to be too uncertain for action but at the same time instituted some internal measures to limit possible damage, if any. These varying levels of precaution allow for the grouping of responses of the countries into three groups as will be elaborated in the following part.

Based on the stance at the EU level and the response to glyphosate-based products internally, the approaches to glyphosates in the EU can be classified as:

a. Opposed the authorization at the EU level

b. Supported authorization at the EU level but introduced cautionary measures internally

c. Supported authorization at the EU level and no internal measures addressing glyphosates

This sub-section shall proceed with a short discussion of each of these approaches, whilst identifying the countries in each group and their characteristics.

a Opposed the authorization at the EU level

These are the 9 countries that maintained their opposition to glyphosate authorization throughout the renewal process at the EU level. As has been mentioned earlier, there does not seem to be a common factor of greater agricultural holdings to explain the greater concern or strong opposition. A possible explanation might be the salience of a high exposure to glyphosates. There are not too many studies or reports recording glyphosate levels in the food chain or the common public. [333]However, the organization Friends of the Earth (Europe) had collected urine samples from urban areas of 18 European countries and published the high

[333] Gillezeau, C., van Gerwen, M., Shaffer, R. M., Rana, I., Zhang, L., Sheppard, L., & Taioli, E. (2019). The evidence of human exposure to glyphosate: a review. *Environmental Health*, *18*(1), 1-14.

percentage of glyphosate presence in such samples (shown in column 5 of Tables 4.3,4.4 and 4.5).[334] These high percentages in urban areas are more alarming as the general population in such areas would not be in direct contact with glyphosates. For instance, glyphosate was detected in 90% of the samples from Malta, which has very meagre agricultural holdings. The publication of these findings and the alarming level of exposure may have motivated Malta's strong stance against glyphosates.

Table 4.4: Member States opposed to authorization of glyphosates as an active ingredient.
Source: Table created based on data from Eurostat, Euro observer, reports from Politico, Euractiv, Pesticide Action Network and Friends of the Earth[335]

[334] Determination of Glyphosate Residues in Human Urine Samples from 18 European Countries. 2018. https://www.foeeurope.org/weed-killer-glyphosate-found-human-urine-across-Europe-130613. Accessed 12 February 2021.

[335] For Tables 4.4. 4.5 and 4.6:
Column 2 ,3,4: Eurostat (online data code: ef_m_farmleg), http://appsso.eurostat.ec.europa.eu/nui/,Accessed 20th February 2021.
Column 5: Determination of Glyphosate Residues in Human Urine Samples from 18 European Countries. 2018. https://www.foeeurope.org/weed-killer-glyphosate-found-human-urine-across-Europe-130613. Accessed 12 February 2021.
Column 6: Simon Marks & Guilia Paravicini, Politico, https://www.politico.eu/article/eu-vote-to-renew-glyphosate-for-10-years-fails/, 25 October 2017, accessed 2nd February 2021.
Column 7: Christina Tati, EU Observer, https://euobserver.com/environment/140042, 27th November 2017, accessed 31st January 2021.
Column 8 : Baum Hedland , https://www.baumhedlundlaw.com/toxic-tort-law/monsanto-roundup-lawsuit/where-is-glyphosate-banned-/, accessed 15th February 2021 ; Sarantis Michaloupoulus, Euractiv , https://www.euractiv.com/section/agriculture-food/news/six-member-states-call-for-glyphosate-alternatives-exit-plan/, 4th January 2018, accessed 15th February 2021; Pesticide Action Network (PAN Europe), https://www.pan-europe.info/press-releases/2016/08/italy-places-important-restrictions-use-glyphosate, 23rd August 2016, accessed 15th February 2021; Guardian.com, https://www.theguardian.com/environment/2019/sep/04/germany-ban-glyphosate-weedkiller-by-2023,4th September 2019, accessed 15th February 2021.

	Member State (1)	Agri. land (2)	%age of holdings <5 Hectare (3)	%age of holdings >50 Hectare (4)	%age of samples containing glyphosate (5)	Vote for 10-year renewal of glyphosate authorisation (6)	Vote for revised renewal of glyphosate for 5 years (7)	Regulation regarding glyphosate-based pesticides (8)
1	Austria	32.40%	31	8.5	20	Against	Against	Law banning all glyphosates tabled in 2019.After two unsuccessful attempts, a partial ban on use in 'sensitive' areas passed in June 2021.
2	Belgium	44.60%	13.9	25.3	55	Against	Against	Signed a letter to European Commission calling for 'an exit plan from glyphosates' Use of glyphosates by individuals banned. Zero pesticide use in Brussels city limits
3	Croatia	27.60%	69.5	3.8	40	Against	Against	-------
4	France	52.40%	24.3	41.3	30	Against	Against	Signed a letter to European Commission calling for 'an exit plan from glyphosates' Sale, distribution and use of Round up banned. 36 glyphosate-based products withdrawn from the market Plan to eliminate glyphosate use by 2021 announced (currently the plan has been made less restrictive)
5	Greece	47.60%	77.3	0.9		Against	Against	Signed a letter to European Commission calling for 'an exit plan from glyphosates' Approved five-year license for Monsanto's Round-up in 2018
6	Italy	43.20%	61.9	4.1		Against	Against	Restriction on glyphosate use for pre-harvest treatment and in public places of frequent use such as parks, gardens, railway edges, school buildings etc
7	Luxembourg	53.70%	16.2	51.8		Against	Against	Signed a letter to European Commission calling for 'an exit plan from glyphosates' Total ban on all glyphosate products began in 3 stage process in February 2020 and has been achieved since December 2020
8	Malta	32.40%	96.5	0	90	Against	Against	Signed a letter to European Commission calling for 'an exit plan from glyphosates' Use of glyphosates banned in public spaces
9	Slovenia	30.70%	59.5	0.9		Against	Against	Signed a letter to European Commission calling for 'an exit plan from glyphosates'

Another noteworthy factor is that most of the Member States opposed to glyphosates have followed it with restrictions on glyphosate use within their territories. 6 countries signed a letter to the European Commission calling for a gradual 'exit plan' from glyphosates, exhorting the Commission to move towards alternative pest management techniques.[336]Luxembourg, currently, has the strongest stance against glyphosates in Europe

[336] Sarantis Michaloupoulus, Euractiv, https://www.euractiv.com/section/agriculture-food/news/six-member-states-call-for-glyphosate-alternatives-exit-plan/, 4th January 2018, accessed 15th February 2021.

with a total ban on all glyphosate-based products. Austria and France have proposed plans to move towards zero glyphosate farming. The two aberrations in the group are Croatia and Greece. Croatia has not introduced any internal measures against glyphosates; however, this is consistent with the behaviour of other countries that have a greater percentage of agricultural holdings under 5 hectares- as there is a lesser use of glyphosate-based products to begin with, regulations may have been deemed unnecessary. Greece is noteworthy for its inconsistency – where on the one hand it co-signed the letter calling for elimination of glyphosates, on the other hand it has also licensed the sale of Monsanto's Round-up for 5 years.

b Supported authorization at the EU level but introduced cautionary measures internally

The second group comprises of those countries that approved the authorization of the glyphosates but introduced plans or measures to restrict glyphosate use within their borders as well. These countries have large shares of agricultural land, some of them in large-scale holdings and continue to reap the benefits of glyphosate use for such kind of large-scale agriculture. Most of the restrictions pertain to limiting non-commercial use or use by private individuals. Thus, exposure of non-professionals and unrelated third parties in public spaces is sought to be curbed. Such actions could be termed as limited (or proportionate) precautionary measures that seek to limit the uncertain threat of glyphosates without forgoing the benefits accruing from them completely. Germany and Sweden are particularly exemplary of this behaviour in the group- the two countries represent the vote change that allowed for the authorization of glyphosates to pass. Initially, Sweden had opposed the 10-year renewal of glyphosate authorization and Germany had abstained from the vote. The two countries changed their vote and approved the authorization when the European Commission proposed a revised authorization for only a 5-year period. The countries not only agreed to the reduced period (enabling a quicker review of the dangers of glyphosates, if any are proved in the interim) but also continued with their plans to limit glyphosate use within their territory.

Table 4.5: Member States that supported authorization but instituted cautionary measures internally.
Source: Table created based on data from Eurostat, Euro observer, reports from Politico, Euractiv, Pesticide Action Network and Friends of the Earth

	Member State (1)	Agricultural land (2)	%age of holdings <5 Hectare (3)	%age of holdings >50 Hectare (4)	%age of samples containing glyphosate (5)	Vote for 10-year renewal of glyphosate authorisation (6)	Vote for revised renewal of glyphosate for 5 years (7)	Regulation regarding glyphosate-based pesticides (8)
1	Czech Republic	45.18%	18.7	27.0	60	Approved	Approved	Agriculture minister announced intention to limit glyphosate use starting 2019, specifically banning use as drying agent
2	Denmark	62.01%	4.4	35.3		Approved	Approved	Ban on private use in urban areas. Ban on using glyphosates for post-emergent crops
3	Germany	47.68%	8.6	30.6	70	Abstained	Approved	Systemic reduction plan to reduce glyphosate use by 2023 approved by Cabinet. Certain retail stores have stopped stocking glyphosate-based products
4	Netherlands	53.31%	20.2	21.5	63	Approved	Approved	All non-commercial use of glyphosates is banned
5	Portugal	39.45%	71.5	4.2		Abstained	Approved	Use of glyphosates is prohibited in all public spaces
6	Spain	52.58%	51.6	10.8	40	Approved	Approved	Wine -growing regions of La Rioja have approved motions against glyphosates
7	Sweden	7.44%	10.5	24.7		Against	Approved	Swedish Chemical Agency announced a plan in 2017 permitting private users to only use 'low-risk ' substances. Glyphosates were assessed not to be 'low-risk'
8	United Kingdom	71.71%	10.2	38.6	70	Approved	Approved	Major retailers, like Homebase, undertook a review of glyphosate-based products after the Roundup litigation in US courts. Several townships and boroughs in the UK have instituted bans and restrictions on glyphosates

c Approved authorization at the EU level and no internal measures addressing glyphosates

The third group constitutes of Member States who have taken no cautionary measures either at the EU or national level. As can be seen in Table 3, most of these countries either have very little agricultural land or even if there is a greater share of agricultural land, most of it is in holdings under 5 hectares. As such, it would seem that the countries have limited use of glyphosate-based products and so possible threats posed by glyphosates have not been a priority in the national discourse.

Table 4.6: Member States that authorized glyphosates at EU level and have no internal measures addressing glyphosates.

Source: Table created based on data from Eurostat, Euro observer, reports from Politico, Euractiv, Pesticide Action Network and Friends of the Earth

	Member State (1)	**Agricultural land (2)**	**%age of holdings <5 Hectare (3)**	**%age of holdings >50 Hectare (4)**	**%age of samples containing glyphosate (5)**	**Vote for 10-year renewal of glyphosate authorisation (6)**	**Vote for revised renewal of glyphosate for 5 years (7)**	**Regulation regarding glyphosate-based pesticides (8)**
1	Bulgaria	46.3%	82.6	4.8		Approved	Approved	-----
2	Cyprus	12.2%	89.6	1	50	Approved	Approved	-----
3	Estonia	23.1%	31.6	17.7		Approved	Approved	-----
4	Finland	7.5%	4	30		Approved	Approved	-----
5	Hungary	58.4%	81.4	3.7	30	Approved	Approved	-----
6	Ireland	64.5%	7.4	18		Approved	Approved	-----
7	Latvia	31.1%	35.2	8.8	55	Approved	Approved	-----
8	Lithuania	47.2%	50	7.2		Approved	Approved	-----
9	Poland	46.9%	54.3	2.4	70	Approved	Approved	-----
10	Romania	58.8%	91.8	0.5		Approved	Approved	-----
11	Slovakia	39.2%	55.7	13		Approved	Approved	-----

The discussion in this section sought to better understand individual motivations and responses within the aggregate EU decision. Based on this background, it will be further examined in the case –studies in the following chapter what role, if any was played by the precautionary principle in the shaping of these different responses.

Chapter 5: Setting Up Case Studies Of National Responses To Glyphosates

5.1 Introduction

In the previous chapter, the research was focused on the EU decision to renew authorization for glyphosates. The last section of the previous chapter elaborated on the individual member-state responses that together made the final decision of the EU commission. Member-states were classified based on a comparison of their response at the EU level and national measures to see if any common explanations for the response can be established. This disentanglement of individual responses and their possible explanations will be used in this intermezzo chapter as a basis for selecting the countries and to identify appropriate questions for the case-studies. Following which, the last section describes the structure to be followed for each of the country –specific studies.

5.2 Choice of countries

The countries have been selected with a view to provide as representative a picture as possible. Case study literature suggests using replicative logic whereby cases are selected according to their appropriate fit with one another.[337] It describes intentionally choosing cases that replicate, counter, add to, or challenge the preliminary theoretical types and framework[338]. Case selection is directed at pursuing informational richness.[339] In other words, cases are not selected for their similarity with one another, but rather their potential to add to our overall understanding. Accordingly, the cases selected are diverse and drawn from the different groups classified in section 2 of this chapter. France would present the story of a highly agrarian country with great reliance on glyphosates but opposed to their use and actively attempting to reduce its reliance on pesticides. The Netherlands provides a counterpoint whereby it seeks to take a less precautionary stance and has approved authorization for glyphosates; nevertheless, it has instituted measures to limit its use and as such has not dismissed potential concerns regarding its safety. The third country choice would ideally be drawn from the group of countries that have approved authorization and not instituted any internal measures. However, the insignificant share of large agricultural

[337] Yin, Robert, K. (2018). 'Case Study Research: Design and Methods', Sage Publications Ltd.; 6th edition.
[338] Meyer, C. B. (2001). A case in case study methodology. Field Methods, 13(4), 329- 352, 333.
[339] Meyer, C. B. (2001). A case in case study methodology. Field Methods, 13(4), 329- 352, 333.

holdings presents a plausible explanation for this response. Lastly, Germany, being the decisive vote change that led to authorization of glyphosates, would add to the case studies to understand what caused it to take a less precautionary stance.

5.3 Identifying questions for the case studies

In this section, the primary questions sought to be answered by the subsequent case studies will be elaborated. These questions can broadly be classified into areas of inquiry mirroring the discussion on the precautionary principle in chapters 2 and 3 of the thesis, *viz* suitability of and reliance on the precautionary principle, value added by precautionary principle to the risk governance decision and criticisms of the precautionary principle. An additional branch of enquiry looks into consistency in the stance of Member-States at the EU and national level. In the following sub-sections, these topics shall be discussed in relation to the glyphosate decision at the Member State level in order to identify the enquiries to be compared across the case-studies. The discussion shall also speculate as to what answers are indicated to these questions based on the hitherto literature review and EU level analysis, as also the interpretation of the possible answers.

5.3.1 Reliance on the precautionary principle

The scientific uncertainty as to the carcinogenicity of glyphosates has been shown to make the present case suitable for the application of the precautionary principle.[340] But the European risk assessment bodies determined that there was no uncertainty in the present case and thus, no precautionary action was warranted.[341]As such, it would indicate that Member States would not be able to avail of the precautionary principle either. However, the regulation does allow for recognizing the precautionary principle in case of scientific uncertainty or ambiguity separately at the Member State level.[342] Even if glyphosates have been authorized by the EU, separate authorization for market access has to be sought for each market-formulation (product) containing glyphosates in every Member State.[343] Rejections for granting such authorization have to be accompanied by technical or scientific

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[340] Röttger-Wirtz, S. (2020). Case C-616/17 Blaise and Others: The precautionary principle and its role in judicial review–Glyphosate and the regulatory framework for pesticides. *Maastricht Journal of European and Comparative Law*, *27*(4), 529-542; See also section 4.3 of Chapter 4.
[341] Röttger-Wirtz, S. (2020). Case C-616/17 Blaise and Others: The precautionary principle and its role in judicial review–Glyphosate and the regulatory framework for pesticides. *Maastricht Journal of European and Comparative Law*, *27*(4), 529-542; See also section 4.3 of Chapter 4.
[342] Regulation no. 1107/2009, Article 52.
[343] Regulation no. 1107/2009, Article 28.

justifications.[344] These justifications may relate to updated scientific data or special geographic, climate or social conditions in the Member State.[345] In putting forth these justifications, the precautionary principle allows for action even if a causal link is not fully established. Thus, in the instant case of glyphosates, where there exist contradictory but plausible scientific opinions about its carcinogenicity, a Member State could rely on the precautionary principle for rejecting an application for access to the national market. Thus, the very first question to be ascertained would be -**Is there an explicit reliance on the precautionary principle at the Member-State level in the decisions regarding authorization of glyphosate-based PPPs?**

The expectation would be that Member States that opposed the renewal of glyphosate authorization would adopt a precautionary approach in authorizing glyphosate-based products. On the other hand, countries that approved the decision would not do so. However, even in the absence of an explicit mention, a precautionary approach could, nevertheless, be discerned from the regulations regarding use and authorization of glyphosate-based products within the State.[346] Such an approach would suggest the possibility of addressing scientific uncertainty without a strict or explicit reliance on the precautionary principle. Thus, a relevant question would be –**If there is no explicit reliance on the precautionary principle, can the approach adopted to the possible threats posed by glyphosates by a Member State be nevertheless viewed as precautionary?** Such precautionary approaches resulting from existing risk governance structures add strength to the need for examining how much value is added by the precautionary principle to decision-making.

5.3.2 Value addition of the precautionary principle

The possibility remains that existing risk governance structures of a country or an inherently risk-averse attitude towards pesticides within a particular country (stemming from extraneous social, geographical, or political factors)[347] might result in a cautious treatment of glyphosates. In that case, the precautionary principle has not aided the decision-making. Thus, a risk management decision consistent with the precautionary principle could be possibly reached without purposefully incorporating the principle. Moreover, an explicit

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[344] Regulation no. 1107/2009, Article 39.
[345] Regulation no. 1107/2009, Article 39.
[346] Opinion of Advocate General Sharpston in case C-616/17 Criminal proceedings against Mathieu Blaise and Others, ECLI:EU:C:2019:190.
[347] Röttger-Wirtz, S. (2020). WP2 D. 2.3 Glyphosate case study, RECIPES project, Maastricht University, 13th April 2020, p. 29-30.

reliance on the precautionary principle does not necessarily indicate the principle having shaped the outcome either – it may be a means to justify a decision motivated by other factors. To this end, it would be useful to elaborate upon the risk governance framework (if any) adopted by the country as regards pesticides, the overall policy of the country in relation to risks posed by pesticides and consistency with/deviation from these factors whilst reaching a decision about glyphosates. At the same time, the administrative texts and the reports on deliberations leading to the eventual policy papers and possible legislative action will also be checked for references to the precautionary principle, if any. It might help determine the direction of influence- if from the policy towards a precautionary approach or from the principle towards the policy. Such an elaboration would help elucidate **if the precautionary approach towards glyphosates is occasioned by the existing risk perception of pesticides in the particular country?**

The perception of how much threat is posed by pesticides may differ in various countries, for instance, based on the nature of agricultural practices and consequent (un)familiarity with pesticides or existing data on exposure to and pervasiveness of a pesticide in the general population. A country that has a great share of large-scale agricultural holdings would be reliant on glyphosate-based pesticides for weed management.[348] Possibly, there would be a higher exposure to glyphosates, not just to those involved in the application of the pesticides.[349]Here potential victims would include those living around areas with a high glyphosate use and sharing water sources with such areas. Any potential threat associated with glyphosate exposure would require multiple avenues to be controlled and monitored. In contrast, countries that do not themselves use glyphosates but perhaps import food from countries that do, would still be exposed to the threat but through a single channel. Consequently, the possibility of a harmful impact on human health would be a greater concern for the country with a higher direct consumption of glyphosate as compared to another country that does not depend on pesticides as much. In this scenario, there would be a difference in the precautionary measures taken in the two countries and perhaps, it would not be appropriate to have a uniform response to the uncertain threat across all Member-States. The varied responses would not be a result of the application of the precaution principle. Nevertheless, a

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[348] E. Bozzini, Pesticide Policy and Politics in the European Union: Regulatory Assessment, Implementation and Enforcement (Palgrave Macmillan, 2017), 2.

[349] Gillezeau, C., van Gerwen, M., Shaffer, R. M., Rana, I., Zhang, L., Sheppard, L., & Taioli, E. (2019). The evidence of human exposure to glyphosate: a review. *Environmental Health*, *18*(1), 1-14.

country with more exposure to the possible threat could rely on the precautionary principle to implement more measures even as the threat remains uncertain.

However, it is not necessary that a country using more glyphosates will view it as a greater threat. An alternate scenario could occur as well – wherein the familiarity with the pesticides and their occurrence in daily lives could result in a possible threat not being viewed seriously- as it would be argued that if indeed there were harmful effects, they would have been observed in those regularly using it. Furthermore, there might already be monitoring systems and a safety infrastructure in place due to regular use. Additionally, there would also stronger economic interests to support continued glyphosate use within the country. On the other hand, possible harm might cause a population unfamiliar with such products to be more opposed to its introduction.[350]In such a case, if stricter measures against glyphosates are implemented by such a country, the precautionary principle is allowing (and critics would argue strengthening[351]) decision-making based on behavioural biases. Thus, understanding the factors shaping the risk perception of pesticides would be relevant to understanding the impact of the precautionary principle. The case studies would seek to answer the question **What are the particular circumstances of a country explaining a possible prioritization of risks posed by pesticides?**

5.3.3 Criticism of the precautionary principle

Even as the precautionary principle has been adopted across the globe, there is significant literature highlighting its undesirability.[352]The criticism of the principle in the literature, *viz* marginalizing scientific decision-making, being too vague to aid decision-making, increasing risk aversion in the bureaucracy, risk/risk trade-offs being ignored, allowing for greater political discretion in scientific decision-making, has been expounded upon in chapter 3 of the thesis. Whilst analysing the EU decision to renew glyphosate authorization, it was seen

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[350] Sunstein, C. R. (2005). Laws of fear: Beyond the precautionary principle (Vol. 6). Cambridge University Press. Sunstein elaborates on how fear of an unknown risk may make it seem more dangerous and cause neglect of ancillary threats arising from addressing an uncertain threat.

[351] Sunstein, C. R. (2005). Laws of fear: Beyond the precautionary principle (Vol. 6). Cambridge University Press.

[352] See chapter 3 for a full discussion; Sunstein, C. R. (2005). Laws of fear: Beyond the precautionary principle (Vol. 6). Cambridge University Press; Nollkaemper, A. (1996). What you risk reveals what you value, and other dilemmas encountered in the legal assaults on risks. The Precautionary Principle and International Law: The Challenge of Implementation. Kluwer Law International, The Hague, 73-94; Miller, H. I., & Conko, G. P. (2004). The Frankenfood myth: how protest and politics threaten the biotech revolution. Greenwood Publishing Group, p. 96. Lenaerts, K. (2004). “In the Union we trust”: Trust-enhancing principles of Community law. Common Market Law Review, 41(2), 317-343.

that decision, was neither guided by the precautionary principle, nor did it exhibit any of the potential criticisms of the principle. It would be fruitful to have a similar study of the decisions at the Member State level to look at if any of the criticisms of the precautionary principle can be seen to occur.

A primary criticism of the principle is its variable nature[353]- Firstly, as it makes it too vague to implement and secondly, it allows for different conclusions about the same product. Furthermore, critics argue that as a differential treatment of similar products is permissible, it allows for possible favourable or unfavourable treatment of only certain manufacturers. Proponents of the principle counter-argue that this flexibility is an asset of the principle- as it allows for adapting to the varied and possibly *ex ante* unascertainable circumstances of each case.[354]As such, different conclusions about the same product do not, by themselves, necessarily highlight a shortcoming of the principle. However, it is still relevant to study the reasons on which such different conclusions are based.

If it cannot be shown that plausible scientific considerations underpin the differential treatment, it may be the result of public perceptions or could be politically motivated. In either case, it would strengthen the case against the precautionary principle- in one case showing that the principle allows for the value judgements of non-experts to marginalize scientific decision-making[355] and in the other that the discretion granted by the precautionary principle to decision-makers increases their vulnerability to political influence. [356]To this end, it would also be worthwhile to elaborate on the composition and procedures adopted by the agency assessing the applications *viz* **does the composition and appointment of the decision-making body make the body susceptible to public perception/industry influence?**

Furthermore, it remains for the decisions to be studied for the occurrence of the connected criticisms of neglecting risk-risk trade-offs and a risk averse bureaucracy. Critics argue that

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[353] Bodansky, D. (1991). Law: scientific uncertainty and the precautionary principle. Environment: Science and Policy for Sustainable Development, 33(7), 4-44.
[354] Ahteensuu, M. (2007). Defending the precautionary principle against three criticisms. Trames, 11(4), 366-381.
[355] Chapman, P. M. (1999). Does the precautionary principle have a role in ecological risk assessment? Human and Ecological Risk Assessment: An International Journal, 5(5), 885-888; Adler, J. H. (2011). The problems with precaution: A principle without principle; Charnley, G. (2000). 1999 Annual Meeting. Past President's Message: Risk Analysis under Fire. RISK newsletter, 20(3).
[356] Bodansky, D. (1991). Law: scientific uncertainty and the precautionary principle. Environment: Science and Policy for Sustainable Development, 33(7), 4-44;

the nature of the problems dealt with by the precautionary principle *viz* uncertain substantial damage could result in a myopic perception of the risk concerned.[357] It could cause the uncertain threat to appear larger than the evidence warrants.[358]Focussing on the immediate threat in question, could cause ignoring the benefits of the product and the harm that could occur due to taking precautionary action against it.[359] Furthermore, if public perception of the associated risk is unbalanced in this manner, risk averse decision-makers may be swayed to decide against the product to garner public support.[360] Thus, an enquiry is required into **whether both the benefits and threats were considered in the assessment; and how each of them were prioritized and addressed in the decision?**

5.3.4 Consistency at EU and National level

An interesting aspect of the study is raised by the two-stage authorization. It could be argued that the two -stage authorization slightly reduces the importance of the decision at the EU level. In spite of the authorization by the EU, member states wary of the negative impacts of glyphosate use could very well deny it within their borders. Market authorization applications for glyphosate-based products could be rejected. Understandably, such rejections would have to be accompanied by an explanation for the rejection.[361]In the present case, as has already been discussed, the precautionary principle would suitably justify rejections. However, it would be a more cumbersome process for the Member State to have to consider every application and provide an opinion and decision on each case.[362] Hence, non- authorization at the EU level would, nevertheless, be the preferred outcome for a member state convinced of the potential threat of glyphosates. On the other hand, Member-States may have approved the authorization at the EU level to help other members who want the continued use of glyphosates, knowing that they themselves can prohibit its use within their borders. To better understand how a Member-State views the potential threat of glyphosates, irrespective of its

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[357] Cass R. Sunstein, Beyond the Precautionary Principle, 151 U. PA. L. REV. 1003, 1024 (2003). Sunstein illustrates how increased regulation can kill more people on net by depriving people of potential benefits.
[358] Cass R. Sunstein, Beyond the Precautionary Principle, 151 U. PA. L. REV. 1003, 1024 (2003). Sunstein illustrates how increased regulation can kill more people on net by depriving people of potential benefits.
[359] Majone, G. (2002). The precautionary principle and its policy implications. JCMS: Journal of Common Market Studies, 40(1), 89-109.
[360]Nollkaemper, A. (1996). What you risk reveals what you value, and other dilemmas encountered in the legal assaults on risks. The Precautionary Principle and International Law: The Challenge of Implementation. Kluwer Law International, The Hague, 73-94; Miller, H. I., & Conko, G. P. (2004). The Frankenfood myth: how protest and politics threaten the biotech revolution. Greenwood Publishing Group, p. 96.
[361] Regulation no. 1107/2009, Article 39.
[362] Phillips McDougall, The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010 to 2014. R&D expenditure in 2014 and expectations for 2019, 2016, pp.3-4.

vote at the EU level, it would be fruitful to study **if there is a change in the stance adopted by Member States at the two levels and if there exists an update in current scientific knowledge or other triggers for such a change?**

5.3.5 Summary

The earlier chapters of the thesis have presented the debate surrounding the desirability of the precautionary principle and raised questions as to if and how the additional value in decision-making or the criticisms can be seen to have occurred. An analysis of the decision to renew authorization of glyphosates by the EU suggests that neither was the precautionary principle relied on nor did the decision suffer from the potential pitfalls of dealing with uncertain threats. However, as was further seen in the previous chapter, glyphosate-based pesticides can be differently regulated and authorized at the Member State level and as such, the decisions at the national level may exhibit a greater role of the precautionary principle. To this end, the thesis will undertake a comparative case study of the responses to glyphosates by Member States within their boundaries in the subsequent chapters. The present section has placed the discussion in chapters 2 and 3 in the context of the Member State level procedures and motivations for pesticide regulation and identified the following questions for investigation and comparison in the country-level case studies:

- Can the approach adopted to the possible threats posed by glyphosates be viewed as precautionary?
- Is there is an explicit reliance on the precautionary principle in the decisions regarding authorization of glyphosate-based PPPs?
- Has there been a change in the stance adopted by Member States at the EU level? Are there updates in current scientific knowledge or other triggers for such a change?
- Is the precautionary approach towards glyphosates occasioned by the existing risk perception of pesticides in the particular country?
- What are the particular circumstances of that country explaining a possible prioritization of risks posed by pesticides?
- Were both the benefits and threats considered in the assessment and how were they prioritized and addressed in the decision?
- Does the composition and appointment of the decision-making body make it susceptible to public perception/industry influence?

5.4 Structure

Having thus detailed the background under which the countries are operating and identified the relevant questions serving the interest of this thesis, this section shall proceed to lay down a common structure for the subsequent case -studies. The section shall elaborate the structure and format for the reporting of the study and the documents and sources to be relied on. The subsequent chapters will focus on individual country responses to glyphosate-based products and comparing the findings in individual studies with the intention of obtaining insights and conclusions as to the working and influence of the precautionary principle in dealing with glyphosates.

5.4.1 Structure of case studies

Whilst studying the individual cases, an approach similar to that outlined in the RECIPES (REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders) project [363] will be adopted. The structure of the approach would be as follows:

I. Describe the legal or regulatory regime governing the use of PPPs within the country- this includes the regulatory agency responsible, its composition, working and prescriptions for their decision- making.

II. Elaborate on the policy regarding pesticide use and reliance, with a view of understanding how risks posed by pesticides are generally characterized and prioritized as against other concerns. These concerns would include those raised by producers of the pesticides, agricultural landowners as well as workers, non-agricultural private users of glyphosates, residents in areas of high glyphosate usage, NGOs and environmental groups representing concerns related to biodiversity and ecosystem protection.

III. Clearly define the threat/ benefit interplay in relation to glyphosates for that specific country. This would require discussing realistic exposure levels based on agricultural intensity, extent of use of glyphosate for other purposes in the country as well as the particular impact of banning glyphosates for that country. The threat may also play out as a trade issue-if the country is an importer of glyphosates, the suppliers may complain of the measures being anti-competitive. If they were originally exporting glyphosates or the

[363] Joe Rini (IASS Potsdam) WP2 Conceptual framework for comparative multiple case study analysis, December 4, 2019. The RECIPES project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824665.

export of food reduces due to reduced food yields, it might cause supply chain issues in other states, ultimately affecting trade relations.

IV. Discuss the decision reached as regards glyphosate-based products in that country. Understandably, the sources and evidence relied on for their decision – including opinions of scientific groups as well as other stakeholders and public participation- would be identified here. Additionally, the discussion would include other executive or legislative actions and judicial decisions in relation to glyphosates and opinions expressed within the country after the decisions.

V. Seek to answer the questions identified in section 5.3 of this chapter based on the information set out in steps I-IV. In answering these questions, the operation of the precautionary principle will be examined through a public choice lens, particularly in the answering whether the criticisms of the principle can be seen to have occurred.

5.4.2 Documents and information sources

The case studies shall rely on legislations establishing regulatory agencies, ombudsman reports on the working of these agencies, texts of judicial decisions arising from glyphosate authorization or banning, executive announcements of the concerned department of the chosen country, publications by environmental organisations in the EU, reporting by EU news sites such as Euractiv and EU observer and national newspapers in the chosen countries.

Chapter 6: Case-studies of the role of precautionary principle in Member-State response to Glyphosates at the national level

6.1 France

6.1.1 Regulatory regime governing the authorization and use of plant protection products

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) is the body responsible for issuing opinions and evaluating applications for authorization of the plant protection products. It is an administrative public establishment accountable to the multiple French Ministries of Health, Agriculture, the Environment, Labor, and Consumer Affairs.[364]

To conduct its health risk assessment mission, ANSES sets up expert committees and working groups, made up of scientists from outside the Agency.[365] Collective expert assessment is carried out according to a procedure that selects and brings together experts from different disciplines around a single topic, takes into account all the available scientific evidence, offers a collective, adversarial forum for any opinions and theories expressed by the experts, and provides advice and/or recommendations that are systematically made public.[366]

The Agency has approximately 800 external experts working in its various groups. They are appointed after analysis of their dossier, consisting of a curriculum vitae and a public declaration of interests (PDI), to assess their competence and any risk of conflicts of interest with respect to the topics to be examined.[367] The Agency also relies on a network of 9 reference and research laboratories located throughout France that are internationally

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[364] French Agency for Food, Environmental and Occupational Health & Safety
14 rue Pierre et Marie Curie / 94701 Maisons-Alfort Cedex / www.anses.fr /

[365] *Examining marketing authorisation applications*. (2022, April 12). Anses - Agence Nationale De Sécurité Sanitaire De L'alimentation, De L'environnement Et Du Travail. https://www.anses.fr/en/content/examining-marketing-authorisation-applications. Last accessed 30 June 2022.

[366] *Autorisationdes produits phytopharmaceutiques, comment ça marche ?* (2022). [Slide show]. INFOGRAPHIC MA AUTHORISATIONS, France. https://www.anses.fr/en/content/examining-marketing-authorisation-applications. https://www.anses.fr/fr/system/files/InfographieAMM.pdf

[367] *Ethical framework*. (2022, January 17). Anses - Agence Nationale De Sécurité Sanitaire De L'alimentation, De L'environnement Et Du Travail. https://www.anses.fr/en/content/ethical-framework. Last accessed 30 June 2022.

recognized in various fields or disciplines and which are in geographical proximity to their respective sectors.[368]

The administrative board of the Agency consists of governmental representatives as well as representatives from social partners, professional bodies, NGOs, and non-profit associations. Voting rights are shared equally between the members.[369] The ANSES follows the assessment guidance provided within the PPP regulation for evaluating applications for market authorization.[370]

6.1.2 Pesticide policy

France had been one of the biggest consumers of pesticides in the EU.[371] In 2008, a dramatic shift in agricultural policy was announced launching the very ambitious *Ecophyto* campaign.[372] The *Ecophyto* campaign launched in 2008 aimed to reduce pesticide use by half in a span of 10 years.[373] It was the most ambitious target set by an EU country with as varied an agricultural system as France, regarded as 'very revolutionary' by NGOs advocating reduced pesticide use.[374]

As part of the *Ecophyto* campaign, funding amounting to nearly half a billion euros was diverted to test innovative farming techniques and encourage farming co-operatives to adapt to more 'organic' technologies.[375] A network of farms, known as DEPHY farms[376], was

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[368] *Ethical framework*. (2022, January 17). Anses - Agence Nationale De Sécurité Sanitaire De L'alimentation, De L'environnement Et Du Travail. https://www.anses.fr/en/content/ethical-framework. Last accessed 30 June 2022.
[369] *Ethical framework*. (2022, January 17). Anses - Agence Nationale De Sécurité Sanitaire De L'alimentation, De L'environnement Et Du Travail. https://www.anses.fr/en/content/ethical-framework. Last accessed 30 June 2022.
[370] *Autorisationdes produits phytopharmaceutiques, comment ça marche ?* (2022). [Slide show]. INFOGRAPHIC MA AUTHORISATIONS, France. https://www.anses.fr/en/content/examining-marketing-authorisation-applications. https://www.anses.fr/fr/system/files/InfographieAMM.pdf
[371] Antier, C., Andersson, R., Auskalniene, O., Barić, K., & Simić, M. (2020). A survey on the uses of glyphosate in European countries. *ENDURE network*, 1-60.
[372]Stolstad, E. (2018, October 11). France's decade-old effort to slash pesticide use failed. Will a new attempt succeed? *science.org*. https://www.science.org/content/article/france-s-decade-old-effort-slash-pesticide-use-failed-will-new-attempt-succeed#:~:text=In%202008%2C%20the%20French%20government,to%20be%20slashed%20in%20half.&text=The%20goal%20%22was%20very%20revolutionary,consumer%20of%20pesticides%20in%20Europe.
[373]Stolstad, E. (2018, October 11). France's decade-old effort to slash pesticide use failed. Will a new attempt succeed? *science.org*.
[374] Stolstad, E. (2018, October 11). France's decade-old effort to slash pesticide use failed. Will a new attempt succeed? *science.org*.
[375] Le Plan Ecophyto 2018, Ministère de l'agriculture et de l'alimentation (France), published 10 September 2008. Available at: https://agriculture.gouv.fr/ministere/le-plan-ecophyto-2018
[376] Lamichhane, Jay Ram, Antoine Messéan, and Pierre Ricci. "Research and innovation priorities as defined by the Ecophyto plan to address current crop protection transformation challenges in France." *Advances in agronomy* 154 (2019): 81-152.

created to test methods requiring lesser chemical use and improve national surveillance of pests and plant diseases. Additionally, taxes were imposed on farm chemicals to decrease sales of pesticides.[377] The plan was met with resistance from farmers who argued that it would impact the competitiveness of the French agricultural sector.[378]

The *Ecophyto* campaign clearly failed in achieving its quantitative goal- on the other hand, national pesticide use increased by 12 % in the period of its operation.[379] However, the French Government pointed to other successful aspects to state that it was not a complete failure.[380] The development of the DEPHY network, deployment of techniques such as mixing crops, planting new varieties and data analysis systems to identify best times to spray, actions targeting gardens and green spaces were seen to have enough of a positive impact as to encourage the Government to launch an updated plan complementing and strengthening the actions already underway.[381]

Ecophyto 2+, a revamped version of the campaign was passed by the French parliament in April 2018 envisaging greater spending for transitioning to minimal pesticide use in agriculture, adding demonstration farms along with increased taxes on pesticides and proposed bans on sale and production of glyphosates as well as 15 other perceived hazardous pesticide ingredients.[382] Within the €71 million framework of national and regional credits, the particular focus is on applied research and innovation transfers. A research program of up to €30 million has been prioritized. The research primarily focuses on two major issues- surveying the exposure to and impact of pesticides on inhabitants near agricultural areas and developing alternatives to glyphosates and neonicotinoids.[383]

This commitment to reducing pesticide use can be seen within local administration as well. In 2019, local legislation was passed by several mayors, banning the use of pesticides within

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[377]Stolstad, E. (2018, October 11). France's decade-old effort to slash pesticide use failed. Will a new attempt succeed? *science.org*.
[378] Stolstad, E. (2018, October 11). France's decade-old effort to slash pesticide use failed. Will a new attempt succeed? *science.org*.
[379] Ministere de l'agriculture et de l'alimentation Communique, 27 July 2018. Available at: https://agriculture.gouv.fr/le-gouvernement-donne-une-nouvelle-impulsion-au-plan-ecophyto.
[380] Ministere de l'agriculture et de l'alimentation Communique, 27 July 2018. Available at: https://agriculture.gouv.fr/le-gouvernement-donne-une-nouvelle-impulsion-au-plan-ecophyto.
[381] Ministere de l'agriculture et de l'alimentation Communique, 27 July 2018. Available at: https://agriculture.gouv.fr/le-gouvernement-donne-une-nouvelle-impulsion-au-plan-ecophyto.
[382]Ecophtyo Plan II, published 20 October 2015. Available at: https://ec.europa.eu/food/plants/pesticides/sustainable-use-pesticides/national-action-plans_en#france
[383] Ministere de l'agriculture et de l'alimentation Communique, 27 July 2018. Available at: https://agriculture.gouv.fr/le-gouvernement-donne-une-nouvelle-impulsion-au-plan-ecophyto.

their towns.[384] The legislation was struck down by the administrative courts as banning pesticide use was ruled to be beyond the regulatory powers of localities.[385] This ruling was met by demands on the French Government across French media as well as social media to introduce legislation requiring 100 to 150 meter buffer zones, particularly close to structures such as schools, pension houses etc. which house more vulnerable populations. Farmers have consistently opposed this legislation, as the proposed zones would reduce about 4.5 million hectares (15% of France's total crop area) of cultivable land. Furthermore, it would leave crops in the wine-growing regions such as Champagne completely defenseless against pests.[386] The proposed measures were protested by the primary French farmers union throughout October 2019 by several nationwide demonstrations.[387] In late October 2019, a public consultation was held by the Government of France collecting close to 53,000 comments.[388] The contents and the conclusion were not made public. However, in December 2019, the government announced a regulation adopting a buffer zone ranging from 5 to 20 meters as had previously been recommended by the ANSES in June 2019. The width of the buffer zone would depend on the classification of the pesticide sprayed, the nature of the surrounding inhabited areas and measures, if any, undertaken to reduce the drift of pesticides whilst spraying.[389] The regulation has faced backlash from both sides of the debate – farmers stated that they would not follow the regulation unless fully compensated for associated

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[384] Pierre-Henri Allain, Forrest Crellin, https://www.reuters.com/article/us-france-agriculture-glyphosate/french-mayors-ban-glyphosate-weedkiller-defying-government-idUSKCN1VC2C1, 22nd August 2019.
[385] Pierre-Henri Allain, Forrest Crellin, https://www.reuters.com/article/us-france-agriculture-glyphosate/french-mayors-ban-glyphosate-weedkiller-defying-government-idUSKCN1VC2C1, 22nd August 2019.
[386] France confirms pesticide buffer of up to 20 metres, The Connexion, 22 December 2019. Available at : https://www.connexionfrance.com/article/French-news/France-confirms-pesticide-buffer-of-up-to-5-20-metres-but-critics-say-this-is-not-enough. Last accessed: 12May 2022.
[387] France confirms pesticide buffer of up to 20 metres, The Connexion, 22 December 2019. Available at : https://www.connexionfrance.com/article/French-news/France-confirms-pesticide-buffer-of-up-to-5-20-metres-but-critics-say-this-is-not-enough. Last accessed: 12May 2022.
[388] *France launches national consultation on pesticide buffer zones,* France 24 with Reuters, 9 September 2019. Available at : https://www.france24.com/en/20190909-france-national-consultation-pesticides-buffer-zones-farming. Last accessed: 10 May 2022.
[389] Order of 27 December 2019 relating to measures for the protection of individuals when using plant protection products and amending the Order of 4 May 2017 relating to the marketing and use of plant protection products and their adjuvants referred to in Article L. 253-1 of the rural and maritime fishing code, NOR: AGRG1937165A, JORF n°0302 of December 29, 2019.

losses;[390] environmentalists opined that the buffer zones are not wide enough (as they had lobbied for at least a 100-metre width).[391]

Since the launch of the *Ecophyto* campaign in 2008, the French Government has had an aggressive stance against pesticide use in general. This stance has been supported by the public at large, in fact many times campaigning for even stricter measures. However, it has been persistently resisted by the French farmer's unions citing that it puts too much pressure on their competitiveness without adequate financial assistance.[392]However, in recent years, the Government seems to be recanting its strong stance and many reversals of intended policy and modifications of established bans are observed- the intention to ban glyphosates has been recanted [393]; the ban on neonicotinoids was modified to help sugar beet farmers through a price slump.[394]

In summary, it may be said that the policy of France towards pesticides tended to be risk averse. The reduction of pesticide use has been a goal in itself. The policy was not limited to controlling the possible negative consequences of improper use but focused on reducing overall pesticide use. However, in recent years, the policy seems to be relaxing a little to allow for controlled use of pesticides (rather than outright bans) whilst continuing the efforts to look for alternatives.

6.1.3 Consideration of Risk vs. Benefit

France has historically been the largest consumer of pesticides and specifically, glyphosates in the EU. This consumption has increased further in the last decade despite ambitious efforts to reduce pesticide reliance. Consequently, in general, greater exposure to glyphosates would be expected. Exposure to glyphosates in urban areas should be minimal as use of products

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[390] *New French Pesticide Buffer Zone Regulation Angers French Farmers and NGOs*, Report approved by Kathryn Snipes, Report No.: FR2020-0003, Global Agricultural Information Network, 16 January 2020. Available at: https://agriexchange.apeda.gov.in/MarketReport/Reports/New_French_Pesticide_Buffer_Zone_Regulation_Angers_French_Farmers_and_NGOs_Paris_France_01-15-2020.pdf

[391] Ibid

[392] Grimonprez, Benoît, and Jean Jacquez. "Pesticide exit policies: what legal tools for financial support for farmers?" (2021).

[393] Magdalena Pistorius, *Reducing pesticide use requires 'coordinated effort', says French minister*, Euractiv France, 24 January 2022. Available at: https://www.euractiv.com/section/agriculture-food/news/reducing-pesticide-use-requires-coordinated-effort-says-french-minister/. Last accessed 10 May 2022.

[394] Sybille de La Hamaide, *France eases ban on bee-threatening pesticide to help sugar sector,* Reuters, 6 October 2020. Available at: https://www.reuters.com/article/us-france-sugar-pesticide-idUSKBN26R34F . Last accessed 10 May 2022.

containing glyphosates is not permitted in gardens, public green spaces, or railway tracks. Even so, glyphosates were detected in 30% of the urine samples collected from urban areas in France.[395] In rural areas, the potential threat associated with glyphosates is felt more in the wine-growing regions because of the intertwined nature of the areas with occupied buildings and the areas with treated crops in vineyards.[396] Apart from vineyards, areas close to large agricultural holdings have also been seen to be affected by the drifting of pesticides during spraying.[397] The urban population and rural non-farmers are , thus, extremely risk averse to any potential threat posed by glyphosates.

On the other hand, French farmers unions have time and again argued that these threats can be controlled for by using appropriate safety measures.[398] Arguably, it would seem that those who would be the most directly exposed to the threat have opposed the ban of glyphosate. However, it must be noted that members of the farmers' union might be holders of agricultural lands and not necessarily themselves the laborers. Small land holders who would also be working their land may be comparatively less reliant on glyphosates for efficiency gains.[399]The farmer's unions have elaborated on the benefits accrued by use of glyphosates. They warn that a sudden transition to no-glyphosate farming would result in halving of yields and consequently, impact food supplies.[400] Furthermore, the French government recognizes that a prohibition of products containing glyphosates should also include not exporting them to other countries.[401] Thus, a transition away from glyphosates would affect the competitiveness of the French agricultural sector through multiple avenues.

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[395] Determination of Glyphosate Residues in Human Urine Samples from 18 European Countries. 2018. https://www.foeeurope.org/weed-killer-glyphosate-found-human-urine-across-Europe-130613. Accessed 12 February 2021.

[396] Magdalena Pistorius, *French agencies to check pesticide exposure of residents in wine-growing areas,* Euractiv France, 21 October 2021. Available at: https://www.euractiv.com/section/agriculture-food/news/french-agencies-to-check-pesticide-exposure-of-residents-in-wine-growing-areas/. Last accessed 10 May 2022.
[397] Magdalena Pistorius, *French agencies to check pesticide exposure of residents in wine-growing areas,* Euractiv France, 21 October 2021. Available at: https://www.euractiv.com/section/agriculture-food/news/french-agencies-to-check-pesticide-exposure-of-residents-in-wine-growing-areas/. Last accessed 10 May 2022.
[398] Bourguignon D., Authorisation of pesticides in the EU, EPRS, European Parliamentary, 2018, 8.
[399] Gerardo Fortuna, '*Conservationist' farmers confirm support for glyphosate renewa*l, EURACTIV, 12 May 2021. Available at: https://www.euractiv.com/section/agriculture-food/news/conservationist-farmers-confirm-support-for-glyphosate-renewal/. Last accessed 10 May 2022.
[400] Bourguignon D., Authorisation of pesticides in the EU, EPRS, European Parliamentary, 2018, 8.
[401] Magdalena Pistorius, *Reducing pesticide use requires 'coordinated effort', says French minister*, Euractiv France, 24 January 2022. Available at: https://www.euractiv.com/section/agriculture-food/news/reducing-pesticide-use-requires-coordinated-effort-says-french-minister/. Last accessed 10 May 2022.

6.1.4 Authorization of glyphosate

Though its opposition to glyphosate authorization at the EU level has been consistent, the position of glyphosate- based pesticides within the country has not been very clear. In recent times, the French Government has recanted its stance at the EU level as well and has indicated that it would support the upcoming renewal of authorization of glyphosates in 2022.[402] Varying decisions relating to glyphosates have come forth through the ANSES, the French legislature and certain courts and are discussed in more detail below:

- ***ANSES***

Even as the renewal decision was underway at the EU level, the ANSES had been approached in February 2016 for their opinion on the divergent assessments about the carcinogenicity of glyphosates. At the time, the ANSES had determined that there wasn't sufficient evidence to reach a conclusion and issued a call for further studies on these specific aspects of the toxicity of glyphosates, as raised by the IARC. Accordingly, it commissioned 6 further scientific studies into the effects of glyphosates in July 2019.[403] Meanwhile, in June 2016, it withdrew the authorization for 126 pesticides that had glyphosate and POE- tallowmine as co-formulants.[404] This withdrawal is in line with the later EU authorization that does not allow for POE-tallowmine as a co-formulant with glyphosates.

Following the 2017 EU relicensing of glyphosates, ANSES undertook the task to review authorization for 64 existing glyphosate-based products in the French markets and the application for 11 new formulations. In December 2019, it withdrew the authorization of 36 PPPs belonging to various manufacturers and refused the application of the 11 new formulations as well. It continues to assess the remaining products. In their report, they rely on the IARC's finding of probable carcinogenicity as well as reports from their reference laboratories about the effects of glyphosate use on ecological balance. In their decision, the

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[402] Magdalena Pistorius, *Reducing pesticide use requires 'coordinated effort', says French minister*, Euractiv France, 24 January 2022. Available at: https://www.euractiv.com/section/agriculture-food/news/reducing-pesticide-use-requires-coordinated-effort-says-french-minister/. Last accessed 10 May 2022.
[403] Study of the carcinogenic potential of glyphosate: ANSES announces the scientific teams selected to conduct additional toxicological studies, ANSES NEWS, 30 April 2020. Available at : https://www.anses.fr/en/content/study-carcinogenic-potential-glyphosate-anses-announces-scientific-teams-selected-conduct-0. Last accessed 10 May 2022.
[404] Withdrawal of plant protection products combining glyphosate and POE-Tallowamine in co-formulation from the French market, ANSES NEWS, 6 June2016. Available at: https://www.anses.fr/fr/content/retrait-des-produits-phytopharmaceutiques-associant-en-coformulation-glyphosate-et-poe Last accessed 10May 2022.

ANSES stated that "*there was not sufficient evidence to show absence of harmful effects on human health and the environment".* They would continue to review the applications of further glyphosate-based PPPs and allow them only if they were satisfied of the absence of harmful effects and if no suitable alternative was available.[405]

- ***French Legislature***

The French legislature had already passed the Labbe Act in 2014.[406]It sought to eliminate the use of pesticides in general by public authorities in public spaces, roadsides, railways etc. and consequently covered the use of glyphosate-based pesticides as well. After the 2017 relicensing, President Macron had announced his government's intention to ban glyphosates for all uses across France within 2 years.[407] However, he has later recanted stating the plan to be too ambitious and the difficulties it would cause to the agricultural sector.[408] Instead, a staggered reduction over a longer time was to be discussed. Environmentalists have bemoaned this as a means of placating growing farmer's protests rather than based on long term health policy.[409] In January 2019, the Labbe act was extended to curtail the sale of glyphosate-products to amateur gardeners. Nevertheless, there has been no legislation affecting agricultural use of glyphosates, neither has a plan for the staggered reduction been put forth. On the other hand, the French Government has said that it intends to support the re-authorization of glyphosate at the EU level as well.[410]

- ***Judicial decisions***

French courts have had to adjudicate on cases stemming from both sides of the debate. In the administrative court at Rennes, a suit was filed by the French Government against the mayor of Langouet, Brittany who had banned glyphosate from their municipality and increased the

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[405] *Opinions issued on expert assessment of regulated products (plant*. (2019, June 17). Anses - Agence Nationale De Sécurité Sanitaire De L'alimentation, De L'environnement Et Du Travail. https://www.anses.fr/en/content/opinions-issued-expert-assessment-regulated-products-plant-protection-products-biocides-and. Last accessed 10 May 2022.
[406] LAW n ° 2014-110 of 6 February 2014 aiming to better regulate the use of phytosanitary products on the national territory.
[407] Elzas, S. (2019, January 25). Macron backs down on pledge to ban glyphosate in France. *RFI*. https://www.rfi.fr/en/environment/20190125-macron-backs-down-pledge-ban-glyphosate-france
[408] Elzas, S. (2019, January 25). Macron backs down on pledge to ban glyphosate in France. *RFI*. https://www.rfi.fr/en/environment/20190125-macron-backs-down-pledge-ban-glyphosate-france
[409] Elzas, S. (2019, January 25). Macron backs down on pledge to ban glyphosate in France. *RFI*. https://www.rfi.fr/en/environment/20190125-macron-backs-down-pledge-ban-glyphosate-france
[410] Brzeziński, B. (2023, November 20). 10 more years: Emmanuel Macron's broken glyphosate promise. *POLITICO*. https://www.politico.eu/article/france-emmanuel-macron-broken-glyphosate-promise-herbicide-european-parliament/

minimum distance between housing and pesticide application to 150 meters.[411] Petitions were submitted by citizens as well as farmer's unions in the area supporting and criticizing the mayor's decision respectively. The French state argued that the mayor was overreaching their jurisdiction by instituting pesticide bans. The court ruled in favor of the French Government. Based on this decision, they contested similar measures by 20 other mayors.

On the other hand, the administrative court at Lyon came down against Round-up 360, banning its sale to professional gardeners and farmers as well. This was following the extension of the Labbe act in January 2019. At the time, market authorization for Round-up 360 had not been revoked by the ANSES. The court explicitly stated that the continued authorization of the product did not respect the precautionary principle under the French Environmental Charter, which allowed potentially harmful products to be banned.[412]

Ultimately, the ANSES has revoked the authorization for most glyphosate-based pesticides and intimated a greater threshold of proof for absence of harm in their future assessments. Nevertheless, the many instances in which various authorities have presented opinions, plans and decisions on the issue provide more opportunities to gather the reasoning therefor. Furthermore, the long ongoing debate also highlights that there is substantial public pressure from both ends.

6.1.5 Role of precautionary principle

In this section, the questions identified earlier will be answered based on the discussion in the earlier sections:

- Can the approach adopted to the possible threats posed by glyphosates be viewed as precautionary?
- Is there is an explicit reliance on the precautionary principle in the decisions regarding authorization of glyphosate-based PPPs?

The initial strong opposition to glyphosates was not explicitly based on the precautionary principle. However, reliance on a precautionary approach is more salient in the recent decisions on the issue. Though there has been no explicit reliance on the precautionary

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[411] Pierre-Henri Allain, Forrest Crellin, https://www.reuters.com/article/us-france-agriculture-glyphosate/french-mayors-ban-glyphosate-weedkiller-defying-government-idUSKCN1VC2C1, 22nd August 2019.
[412] Barbara Cassasus, *French court bans sale of controversial weedkiller,* NATURE, 24 January 2019. Available at :https://www.nature.com/articles/d41586-019-00259-x#:~:text=France%20is%20among%20the%20nations,fierce%20arguments%20between%20member%20states. . Last accessed 10 May 2022.

principle by the ANSES, a precautionary approach is evidenced in that the ANSES required proof of absence of harm rather than the other way around. The only explicit reliance on the precautionary principle has been in the decision in the administrative court of Lyon. Though it was expected that the decision would lead to cases in other courts using the Lyon decision as a persuasive argument to ban the use of Roundup 360, there has not been a reiteration of this line of reasoning. It must be noted that the judicial decision was prior to the ANSES 's decision to revoke authorization for most glyphosate-based pesticides and may have caused the ANSES to consider the precautionary principle in its assessment. The reason for the most recent recantation of opposition to glyphosates has been given to be the difficulty of transitioning completely to no glyphosate farming.

- Has there been a change in the stance adopted by Member States at the EU level? Are there updates in current scientific knowledge or other triggers for such a change?

Immediately following the EU level authorization, there was no change in the French government's views that glyphosate use should be banned. The opinion of the ANSES regarding the IARC's finding of possible carcinogenicity also strengthened since 2016. The agency stated this to be a result of further comparative studies of the assessments of the EFSA and the IARC and understanding the reasons for their divergent conclusions. Furthermore, it also mentioned studies from their national reference laboratories suggesting greater exposure to glyphosates in France, causing ecological imbalances and health hazards apart from cancer.

In the following years, there has been a change in opinion as to how immediately a reduction in glyphosate use can be effected. This change may be seen as the result of financial obstacles for farmers in transitioning immediately to no glyphosate farming. Thus, the change in stance has not been caused by updates in scientific knowledge as to the potential threat posed by glyphosates.

- Is the precautionary approach towards glyphosates occasioned by the existing risk perception of pesticides in the country?
- Do the circumstances of that country explain a possible prioritization of risks posed by pesticides?

The approach towards glyphosates is consistent with the pesticide policy of France, which has prioritized the risk associated with over-reliance on pesticides. This risk was not prompted by any specific health concerns associated with a particular component. On the other hand, reduction of pesticide use was seen as a component of moving towards

sustainable agricultural techniques. Considering that pesticides by their very objective are toxic to some extent, reducing their prevalence was seen as a desirable goal. The prioritization of reducing pesticide use in France can be explained as the result of two factors- the large share of agriculture (creating more avenues of pesticide dispersion) and immense reliance on pesticides as compared to other countries. As such, the exposure levels to pesticide and accumulation of residues were a relevant concern on the national stage.

Thus, the initial risk perception of pesticides in general was not the consequence of an application of the precautionary principle. However, this initial risk-aversion was strengthened when the finding of possible carcinogenicity of glyphosates was added to the arguments against pesticide use. In this case, the precautionary principle allowed for risk-averse decisions even as the scientific opinion on its potential threat remained divergent. It served to strengthen a legal justification whilst the decision-making remained based on the existing risk-perception. Thus, the precautionary approach towards glyphosates could be attributed to the existing risk-perception related to pesticides in France.

- Does the composition and appointment of the decision-making body make it susceptible to public perception/industry influence?

The decision-making body in this case, ANSES, as has been discussed earlier has external experts from various fields appointed for a single topic after analyzing conflicts of interests. The administrative body of the agency has equal representation and equal voting rights for different sections of the public. In sum, the composition does not seem to allow for influence from a certain group.

- Were both the benefits and threats considered in the assessment and how were they prioritized and addressed in the decision?

The benefits accrued by glyphosate use have not been ignored by the French Government. Reduced food supplies and strain on the agricultural sector in the absence of glyphosate caused the French Government to reconsider their plan of banning them within three years. They have instead opted for a more staggered transition to address this threat. The revised plan under *Ecophyto 2* + makes provisions for financial and infrastructural help for transitioning to more organic techniques of pest management. The costs of such a transition are not insignificant. However, these costs are not only to avoid possible health impacts, but

as part of a long-term policy towards sustainable development. Thus, it appears that the French government has not neglected the risk/risk trade-off in the situation.

At the level of the authorizing agency, the decision seems to be tilted more towards addressing the possible threat posed by glyphosate. However, it must be noted that the ANSES is not required to consider the benefits of a product, rather if it is safe enough to be placed on the market. Even so, it has added an exception of allowing those glyphosate-based PPPs that do not have a suitable alternative- suggesting that the risk/risk trade-off has not been completely neglected.

6.1.6 Conclusion

- ***Value addition by the precautionary principle***

Considering the discussion till now, it may be surmised that the precautionary principle's role has been in providing a stronger basis for regulatory action based on the existing risk-perception of glyphosates in France. The greater aversion to pesticides is not, by itself, occasioned by the application of the principle.

The support for glyphosates from farmers is interesting in that those most directly exposed to the possible threat, are against the elimination of the threat. This seeming contradiction may be explained in 2 ways. Firstly, it may be that familiarity with glyphosates may cause them to perceive the risk as less severe. On the other hand, the support may be coming from Farmer's unions composed of agricultural landowners and not the agricultural laborers exposed directly to the threat. However, there is not a discernible opposition from specifically agricultural laborers either. Thus, the application of the precautionary approach has not necessarily allowed for the wishes of those most affected by an uncertain threat to be reflected. This belies one of the value additions claimed by proponents of the precautionary principle.

- ***Criticisms of the precautionary principle***

On the other hand, the criticisms of the principle cannot be seen to have occurred in the risk management decisions at the national level. The precautionary principle did not prompt the aversion to pesticides in the first instance. Albeit it did allow for precautionary regulatory action against glyphosates, the regulatory action was nevertheless, staggered and allowed for exceptions – indicating that the risk/risk trade-off had not been ignored when faced with a potential threat to human health. Furthermore, precautionary action included investments

towards alternative techniques and substitutes for glyphosates. Thus, it simply redirected the innovation efforts rather than cause stagnation. The ultimate decision regarding market authorization and the proposed plan to phase out glyphosate use is based on plausible scientific evidence, is cognizant of the greater exposure level to the threat in France, asks for further research, and does not neglect the risk/risk trade-off.

However, it cannot be ignored that the precautionary principle was cited as justifications for actions determined as governmental over-reach at the Municipal level. Several municipal officers relied on the precautionary principle to make rules beyond their competency. The fact that the citizens in those municipalities supported these decisions further points toward the principle enabling regulatory overreach. However, these occurrences have to be taken with a grain of salt. The regulatory measures were declared unlawful by administrative courts in the area, as they went well beyond the constitutionally granted competency of the municipal executives. Thus, constitutional measures for checks and balances did control any possible regulatory overreach.

Furthermore, such overreach can be seen at the municipal level and not the national level- suggesting that this criticism of the principle may be remedied by reiterating the level of government for whom the precautionary principle is available as justification for regulatory measures.

6.2 Netherlands

6.2.1 Regulatory regime governing the authorization and use of plant protection products

Evaluation and approval for plant protection products in the Netherlands is the responsibility of the ‘College voor de toelating van gewasbeschermingsmiddelen en biociden’ (Ctgb) or the Board for Authorization of Plant Protection Products and Biocides.[413] It began as a secretarial office instituted to support a committee of scientists advising the Dutch government under the Pesticides Act of 1962.[414] The present-day independent agency was established under the Plant Protection Products and Biocides Act ,2007(Wgb).[415] By assessing and deciding on applications for the authorization of crop protection products and biocides it contributes to

[413] *Government policy*. (n.d.). RIVM. https://www.rivm.nl/en/chemkap/fruit-and-vegetables/government-policy.Last accessed 30 November 2023.
[414] Zadoks, J. C. (1991). A hundred and more years of plant protection in the Netherlands. *Netherlands Journal of Plant Pathology*, *97*, 3-24.
[415] Wet gewasbeschermingsmiddelen en biociden, 2007.

the responsible use of these products and consequently to maintain the effectiveness, predictability and safety of the food chains.[416] It operates as an intermediary between the general public, society, industry and politicians, farmers and producers, pest management professionals and infection control specialists. [417]

In addition to chapter 2 of the 2007 Act, the working and mandate of the agency is detailed in the Plant protection products and biocidal products decree[418] and Plant protection products and biocidal products Regulation[419]. Furthermore, the Ctgb has published an Evaluation manual[420] to set forth clearly the application process specific to the Netherlands and the assessment frameworks to be employed. Matters concerning its independent status and integrity are governed by the Framework Act on Independent Administrative Bodies ,2006[421] and the provisions governing the relationship between public bodies and individual citizens and businesses in the General Administrative Law[422] of the Netherlands. The Ctgb is bound by general European regulations and policy rules, and it is possible to test the correctness of the Ctgb's decisions via the objection procedure.[423]

To apply for authorization, a producer has to submit a file with studies showing the safety of their product as regards farmers, contractors, consumers, animals, the environment, and water. The studies have to be conducted by independent laboratories in compliance with Good Laboratory Practice (GLP).[424] These laboratories have to have been inspected regularly

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[416] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2017, September 28). *Mission, vision and strategy*. About the Ctgb | Board for the Authorisation of Plant Protection Products and Biocides. https://english.ctgb.nl/about-ctgb/mission-vision-and-strategy. Last accessed 30 November 2023.
[417] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2017, September 28). *Mission, vision and strategy*. About the Ctgb | Board for the Authorisation of Plant Protection Products and Biocides. https://english.ctgb.nl/about-ctgb/mission-vision-and-strategy. Last accessed 30 November 2023.
[418] Decree of 5 September 2007, containing further rules regarding plant protection products and biocides (Plant Protection Products and Biocides Decree).
[419] Regulation of the Minister of Agriculture, Nature and Food Quality of 26 September 2007, no. TRCJZ/2007/3100, containing further rules regarding plant protection products and biocides
[420] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2024, March 4). *Evaluation Manual v. 2024-1*. Assessment Framework PPP | Board for the Authorisation of Plant Protection Products and Biocides. https://english.ctgb.nl/plant-protection/documents/assessment-framework-ppp/2024/03/01/em-2024-1-march
[421] Regels betreffende zelfstandige bestuursorganen (Kaderwet zelfstandige bestuursorganen),2006.
[422] Act of 4 June 1992, containing general rules of administrative law (General Administrative Law Act)
[423] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2021, December 6). *Klachtenregeling*. Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/organisatie/klachten. Last accessed 30 November 2023.
[424] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2023, September 22). *Hoe werkt het toelatingsproces?* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/hoe-werkt-het-toelatingsproces

by the Dutch Healthcare and Youth Inspectorate (IGJ).[425] Based on the files submitted and the assessment framework in the Evaluation manual either the secretariat of the Ctgb or a third-party collaborator will present a draft decision to the Board.[426]

In assessing a product, the secretariat looks at its effectiveness for its stated purpose, its impact on humans (toxicology) and its inherent physio-toxic properties. The hazard is viewed in combination with exposure and residue levels determined through data from other independent bodies and registrars such as the REACH.[427] The risk assessment is undertaken in a graduated manner in several steps (called tiers).

The first step – tier 1 – is a coarse-grained approach to exposure and effect concentrations based on laboratory studies with high safety factors.[428] If within the first tier, a safe application cannot be seen, the risk is studied further to determine its exact nature and the possibility to control it.[429] Higher tiers of assessment may involve research at population level in combination with modelling or landscape modelling.[430] Occasionally studies on representative species of animals, insects, birds and fish are used.[431] A safety standard of one-fifth to one-hundredth of the pre-determined safe value is viewed as permissible, due to variations within a species and to translate the results to other species.[432] Authorization requires the risk to fall within the safety margins established at the European level as well as those specifically established for the Netherlands.[433] Additional measures may be prescribed,

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[425] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2023, September 22). *Hoe werkt het toelatingsproces?* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/hoe-werkt-het-toelatingsproces
[426] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2023, September 22). *Hoe werkt het toelatingsproces?* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/hoe-werkt-het-toelatingsproces
[427] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2020, December 4). *Hoe beoordeelt het Ctgb risico's voor mens, dier en milieu?* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://ctgb.nl/over-ctgb/beoordeling-risico
[428] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2024, March 4). *Evaluation Manual v. 2024-1.* Assessment Framework PPP | Board for the Authorisation of Plant Protection Products and Biocides, chapter 2.
[429] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2024, March 4). *Evaluation Manual v. 2024-1.* Assessment Framework PPP | Board for the Authorisation of Plant Protection Products and Biocides, chapter 2.
[430] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2024, March 4). *Evaluation Manual v. 2024-1.* Assessment Framework PPP | Board for the Authorisation of Plant Protection Products and Biocides, chapter 2.
[431] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2024, March 4). *Evaluation Manual v. 2024-1.* Assessment Framework PPP | Board for the Authorisation of Plant Protection Products and Biocides, chapter 2.
[432] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2024, March 4). *Evaluation Manual v. 2024-1.* Assessment Framework PPP | Board for the Authorisation of Plant Protection Products and Biocides, chapter 2.
[433] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2023b, December 8). *Wanneer laat het Ctgb een middel toe?* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/hoe-veilig-is-een-toegelaten-middel. Last accessed 20 December 2023.

such as the use of special spray nozzles, to reduce the risks even further.[434] Assessments are done on the assumption that product is being used correctly.

The Board deliberates over the draft decision before making any authorization final and discusses in particular the need for limitations or specific safety prescriptions relating to proper use. If it finds it is not possible to get the risk posed by the product within the safety margins, even by implementing additional usage limitations or safety measures, then it rejects the application.[435] Otherwise, the approval for placing on the market along with a registration number and any such prescription as to usage limitations is published by the board.[436] All products have to display this number and any instructions as to use prominently on all their packaging. The monitoring of the use and observance of proper safety measures and spraying techniques is under the ambit of De Stichting Kwaliteitseisen Landbouwtechniek (SKL) separate from the Ctgb.[437] There is a provision for granting temporary emergency authorizations without undergoing the assessment framework if it is seen as the only reasonable solution to an urgent and dangerous special circumstance.[438] Such authorization is for a limited and controlled use of the product for a maximum of 120 days.[439]

The Board does not develop the assessment framework itself. Neither does it set the maximum residue levels or acceptable levels of exposure. It follows the standards set by the European Union and under the PPP regulation at the EU level, albeit with certain adaptations specific to agricultural practices in the Netherlands.[440] However, it does contribute to the evolution of the framework by identifying and communicating any gaps it encounters in the framework in the course of its operations.[441]

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[434] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2023b, December 8). *Wanneer laat het Ctgb een middel toe?* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/hoe-veilig-is-een-toegelaten-middel. Last accessed 20 December 2023.
[435] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2023b, December 8). *Wanneer laat het Ctgb een middel toe?* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/hoe-veilig-is-een-toegelaten-middel. Last accessed 20 December 2023.
[436] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2023b, December 8). *Wanneer laat het Ctgb een middel toe?* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/hoe-veilig-is-een-toegelaten-middel. Last accessed 20 December 2023.
[437] *Government policy*. (n.d.). RIVM. https://www.rivm.nl/en/chemkap/fruit-and-vegetables/government-policy.Last accessed 30 November 2023.
[438] Art.38, Wgb 2007.
[439] Art.38, Wgb 2007.
[440] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2017, September 28). *Mission, vision and strategy*. About the Ctgb | Board for the Authorisation of Plant Protection Products and Biocides..
[441] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2017, September 28). *Mission, vision and strategy*. About the Ctgb | Board for the Authorisation of Plant Protection Products and Biocides..

The Board consists of a council and a secretariat with about 150 members drawn from their specific areas of expertise. A third of the members are PhD holders and 85% have completed a university degree.[442] The Ctgb as an independent public body is hierarchically detached from any ministry.[443] Different ministries that may seek advice and consultation are rather its clients. The powers and scope of operations of the employees of the Board are administered in the 'Mandate, powers of attorney, authorization and representation Ctgb Decree 2018, which allows for the actions necessary for the procedures related to assessment of PPPs.

For the purposes of integrity and transparency, the Ctgb applies a code of conduct for its employees, members, and deputy members.[444] Conflicts of interests are sought to be prevented through individual reporting statements that are accessible to all on its website.[445] The Framework Act for Independent Administrative Bodies stipulates that additional functions of board members and deputy board members are made public. For the board members, this primarily relates to their regular positions at Research Institutes or Universities. However, it also pertains to any other management positions that may be held by them. To foster transparency, all the studies relied upon for reaching a decision, the assessment reports, the draft decisions and the final decisions are published as publicly available documents by the Ctgb.[446]

The Ctgb sometimes has to rely on external expertise for its assessments. It does so in collaboration with third parties, referred to as Evaluating Authorities (EIs). Such evaluating authorities are bound by the same framework and procedures as the Ctgb in carrying out the delegated work. The Ctgb and such authorities are required to enter into Service Level agreements[447] detailing the procedural framework, quality assurance and declarations of confidentiality and conflict of interest with regard to the assignments. During the execution of

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[442] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2024a, March 4). *College en secretariaat.* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/organisatie. Last accessed 30 November 2023.
[443] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2024a, March 4). *College en secretariaat.* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/organisatie. Last accessed 30 November 2023.
[444] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2024a, March 4). *College en secretariaat.* Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/organisatie. Last accessed 30 November 2023.
[445] Ctgb gedragscode integriteit, vastgesteld MT d.d. 24 oktober 2017.
[446] Ctgb gedragscode integriteit, vastgesteld MT d.d. 24 oktober 2017.
[447] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2022, February 2). *Voorkomen* belangenverstrengeling *bij samenwerking met derden*. Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/organisatie/samenwerken-met-derden. Last accessed 30 November 2023.

assignments, the EI employee undertakes to refrain from accepting work from third parties in the field of the assignment.[448]

As a tariff-driven public body, the Ctgb is responsible for covering the cost of its own operations.[449] These are covered through fees for processing applications to authorize plant protection products and biocides, an annual fee paid by authorization holders and other activities such as policy advice for ministries.[450]

6.2.2 Pesticide policy

The Netherlands has had a high input of pesticides, primarily in horticulture.[451] Simultaneously, since the 1990s it has been consistently making a concerted effort towards reducing pesticide residue.[452] One of the major drivers for these efforts were drinking water production problems in 1993-94 caused due to high concentrations of pesticides in water sources.[453] The pesticide policy of the Netherlands can be understood broadly in 3 stages, each with increasingly wider means of achieving lesser reliance on pesticides.

- ***1991- 2001: National covenant on pesticide use reduction (1997)***

The first spurt of reduction in pesticide use was triggered by a national voluntary agreement (covenant) between governmental bodies in 1997 (Bestuurlijke afspraken uitvoering Meerjarenplan Gewasbescherming Openbaar Groen (MJPG-OG), 1997)[454]. The covenant was among others signed by the national government and the three umbrella organisations of

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[448] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2022, February 2). *Voorkomen* belangenverstrengeling *bij samenwerking met derden*. Over Ctgb | College Voor De Toelating Van Gewasbeschermingsmiddelen En Biociden. https://www.ctgb.nl/over-ctgb/organisatie/samenwerken-met-derden. Last accessed 30 November 2023.
[449] Tarievenbesluit Ctgb 2017, *Staatscourant (2016)*, stcrt-2016-70038.
[450] Tarievenbesluit Ctgb 2017, *Staatscourant (2016)*, stcrt-2016-70038.
[451] De Jong, F. M., De Snoo, G. R., & Loorij, T. P. (2001). Trends of pesticide use in The Netherlands. *Mededelingen (Rijksuniversiteit te Gent. Fakulteit van de Landbouwkundige en Toegepaste Biologische Wetenschappen)*, *66*(2b), 823–834.
[452] *Government policy*. (n.d.). RIVM. https://www.rivm.nl/en/chemkap/fruit-and-vegetables/government-policy.Last accessed 30 November 2023.
[453] Sluijsmans, J. J. L., & Drijver, C. A. (1997). Terugdringen van het gebruik van chemische onkruidbestrijdingsmiddelen op verhardingen met behulp van detectie-spuittechniek (Reduction chemical weed control on pavements with sensor technology).
[454] MJPG-OG (Bestuurlijke afspraken uitvoering Meerjarenplan Gewasbescherming Openbaar Groen) (1997) *Ministerie van Landbouw, Natuurbeheer en Visserij, Ministerie van Ruimtelijke Ordening en Milieu, Ministerie van Verkeer en Waterstaat, Ministerie van Defensie, Ministerie van Volksgezondheid, Welzijn en Sport, Stichting GroenRaad, Vereniging van Nederlandse Gemeenten, NS/Railinfrabeheer, Unie van Waterschappen, Bosschap en Vereniging van samenwerkingsverbanden in de Openluchtrecreatie (OSO) (Covenant Implementation Multi Year Crop Protection Plan Urban Green)* (in Dutch).

municipalities, provinces, and water boards.[455] The two main objectives of the agreement were to reduce use by 43% in 2000 and to reduce emission to the environment by 90% in comparison with the situation in the period 1984–1988.[456] The covenant was coupled with a regulation limiting the use of soil fumigants to 5 times a year. [457]The covenant was evaluated in 2001, where it was concluded that the use objective was met (a 69% reduction as compared to pesticide use in 1984 was noted), but not the emission objective.[458]

- ***2001-2012: Integrated pest management plans and market-driven responses***

The evaluation in 2001 led to a multi-pronged approach towards integrated pest management.[459]Integrated pest management (IPM), with a customized plan for each crop, was recognized as part of the national policy.[460] An annual IPM-plan has to be drawn by all farmers and a log book has to be maintained to record deviations from it.[461]A new covenant was agreed upon between farmers, chemical industry and ministries with the specific objective of reducing pesticide risk for surface water in the period 2004-2020 by 95%.[462]Consequently, regulations establishing buffer zones along water courses were introduced. The area of the buffer zones varies depending on the kind of crop cultivated and

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[455] Kristoffersen, P., Rask, A. M., Grundy, A. C., Franzen, I., Kempenaar, C., Raisio, J., ... & Zarina, L. (2008). A review of pesticide policies and regulations for urban amenity areas in seven European countries. *Weed Research*, *48*(3), 201-214, 208.

[456] Kristoffersen, P., Rask, A. M., Grundy, A. C., Franzen, I., Kempenaar, C., Raisio, J., ... & Zarina, L. (2008). A review of pesticide policies and regulations for urban amenity areas in seven European countries. *Weed Research*, *48*(3), 201-214, 207.

[457] National Action Plans, Integrated Pest Management and the Common. (2017, March 10). PAN Europe. *https://www.pan-europe.info/events/conferences/past-events-2005-2015/national-action-plans-integrated-pest-management-and-common*

[458] Kristoffersen, P., Rask, A. M., Grundy, A. C., Franzen, I., Kempenaar, C., Raisio, J., ... & Zarina, L. (2008). A review of pesticide policies and regulations for urban amenity areas in seven European countries. *Weed Research*, *48*(3), 201-214, 208.

[459] National Action Plans, Integrated Pest Management and the Common. (2017, March 10). PAN Europe. *https://www.pan-europe.info/events/conferences/past-events-2005-2015/national-action-plans-integrated-pest-management-and-common*

[460] National Action Plans, Integrated Pest Management and the Common. (2017, March 10). PAN Europe. *https://www.pan-europe.info/events/conferences/past-events-2005-2015/national-action-plans-integrated-pest-management-and-common*

[461] National Action Plans, Integrated Pest Management and the Common. (2017, March 10). PAN Europe. *https://www.pan-europe.info/events/conferences/past-events-2005-2015/national-action-plans-integrated-pest-management-and-common*

[462] Convenant Duurzaam Beheer (2001) *Zeeuwse overheden samen sterk bij het afbouwen van chemische onkruidbestrijding. Gemeenten Borsele, Hulst, Kapelle, Noord-Beveland, Sas van Gent, Schouwen-Duiveland, Terneuzen, Tholen and Veere, Waterschap Zeeuwse Eilanden, Waterschap Zeeuws-Vlaanderen, Rijkswaterstaat directie Zeeland, Provincie Zeeland and Havenschap Zeeland Seaports, NL (Covenant Sustainable Weed Control; Zeeland governments cooperate in reduction of chemical weed control)*. Provincie Zeeland, Middelburg, the Netherlands

the machinery being used.[463]Furthermore, reduction goals and corresponding measures relating to non-chemical weed control were introduced for hard surfaces in urban areas.[464]

Simultaneously, the Dutch market-players also found it advantageous in this period to align themselves with the goal of pesticide reduction.[465] Since 2002, the Dutch public was made more cognizant of the impacts of pesticides and residue-levels in their food and water through Milieu Défense's programme '*weet wat je eet'*.[466] Domestically, the major Dutch supermarket chains committed to goals of being residue-free or lower maximum residue limits.[467] Consequently, applications from farmers for Good Agricultural Practice (GAP) certificates gained traction post- 2000 to maintain supply contracts with these chains.[468] Such practices include more non-chemical weed control and avoiding large scale spraying of pesticides. Another advantage of the GAP certificates was their global recognition, boosting the Dutch position in international trade.[469]Thus, pesticide use reduction was seen as an economically desirable outcome for farmers.

- ***2012-2022: Dutch Action Plan on sustainable plant protection[470] (2012)***

The requirement of the Directive 2009/128/EC on sustainable pesticide use for a national action plan coincided with the integral review of Dutch plant protection policy.[471] Consequently, a national action plan was drawn incorporating inputs from civil society

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[463] Directive, W. F. (2003). Common implementation strategy for the water framework directive (2000/60/EC). *Guidance document*, *7*.
[464] Kempenaar, C., & Spijker, J. H. (2004). Weed control on hard surfaces in The Netherlands. *Pest Management Science: formerly Pesticide Science*, *60*(6), 595-599.
[465] National Action Plans, Integrated Pest Management and the Common. (2017, March 10). PAN Europe. *https://www.pan-europe.info/events/conferences/past-events-2005-2015/national-action-plans-integrated-pest-management-and-common*
[466] Ensie. (n.d.). Weet wat je eet - Geen gif op groente en fruit. Milieudefensie. *https://milieudefensie.nl/archief/weet-wat-je-eet-geen-gif-op-groente-en-fruit*. Last accessed 30 November 2023.
[467] Ensie. (n.d.). Weet wat je eet - Geen gif op groente en fruit. Milieudefensie. *https://milieudefensie.nl/archief/weet-wat-je-eet-geen-gif-op-groente-en-fruit*. Last accessed 30 November 2023.
[468] National Action Plans, Integrated Pest Management and the Common. (2017, March 10). PAN Europe. *https://www.pan-europe.info/events/conferences/past-events-2005-2015/national-action-plans-integrated-pest-management-and-common*
[469] National Action Plans, Integrated Pest Management and the Common. (2017, March 10). PAN Europe. *https://www.pan-europe.info/events/conferences/past-events-2005-2015/national-action-plans-integrated-pest-management-and-common*
[470] Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur
[471] Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur, 1.

organisations, the private sector and the framework prescribed by the Directive which achieves sustainable use through reducing risks and adverse impacts and promoting integrated pest management and alternative management methods or techniques (e.g. non-chemical methods).[472]

Government bodies, the private sector and civil society organisations are jointly responsible for implementing the action plan, though its primary responsibility depends on the latter two.[473] The method chosen is a supply chain approach, comprising actions throughout the chain.[474]Area-based regulations may be used to supplement the approach where water quality standards/pesticide residue limits are exceeded locally.[475]

The action plan continues to build on the certificate of competence program for those handling as also distributing and selling pesticides.[476]Aerial spraying and sale of toxic, very toxic, carcinogenic, mutagenic or toxic for reproduction pesticides to non-professional users is outright banned.[477]Most other measures relate to upkeep of equipment, proper handling and storage and the dissemination of correct information as to its handling and side -effects.[478]A special focus is given to the protection of the river basin systems and reducing run-off to drinking water.[479]Within the agricultural domain, measures requiring use and upkeep of technology reducing drift to surface water, larger buffer zones and closed water systems for

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[472] Directive 2009/128/EC
[473] Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur, 3.
[474] Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur, 3.
[475] Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur, 3.
[476] Artikel 5-6, Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur.
[477] Artikel 5-6, 9, Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur.
[478] Artikel 7, 8,10,13, Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur.
[479] Artikel 11, Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur.

glass house agriculture have been mandated.[480]Outside the agricultural domain, the emphasis is using non-chemical means on hard surfaces as far as possible.[481]As a whole, the plan attempts to anticipate risks and mitigate them by controlling emissions and promoting proper use and storage.

It is noteworthy that a preference for self-regulation by stake holders rather than a command-and-control regulation underpins all these stages. Further, the focus in goal setting is on the residue levels.[482]Reduction in usage or dosage per hectare is thought of as a means of achieving lower emissions; not an end goal in itself.[483]

6.2.3 Consideration of Risk vs. Benefit

The consistently reduced pesticide usage in the Netherlands would mean a reduced exposure to glyphosates and consequently, a reduced risk. However, it has time and again been identified that the Netherlands faces a specific problem of drinking water production being affected by pesticide residues.[484] About 40% of the drinking water in the Netherlands is drawn from surface water.[485] This share is estimated to increase in the future.[486] Even after the 30 year long efforts , the Dutch action plan has not achieved its goals for reduced residue levels in water sources.[487] Studies from the Netherlands Environmental Assessment Agency

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[480] Artikel 12, Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur.
[481] Artikel 13, Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur.
[482] De Jong, F. M., De Snoo, G. R., & Loorij, T. P. (2001). Trends of pesticide use in The Netherlands. *Mededelingen (Rijksuniversiteit te Gent. Fakulteit van de Landbouwkundige en Toegepaste Biologische Wetenschappen)*, *66*(2b), 823–834.
[483] Artikel 15, Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur.
[484] Aarnink, W. H. B., van der Bolt, F. J. E., Merkelbach, R. C. M., & Westein, E. (1996). *Belasting van grond- en oppervlaktewater met bestrijdingsmiddelen in de stroomgebieden van de Beerze, Reusel en Rosep* (No. 456). DLO-Staring Centrum; PBL Netherlands Environmental Assessment Agency, & Ligtvoet, W. (2008). *Evaluation of the Water Framework Directive in the Netherlands; costs and benefits*. PBL Netherlands Environmental Assessment Agency.
[485] van Volkshuisvesting, M. (2000). Ruimtelijke Ordening en Milieubeheer (2001). Nota ruimte. Available online at: https://www. ser. nl/~/media/db_adviezen/2000_2009/2004/b22768% 20pdf. ashx.
[486] van Volkshuisvesting, M. (2000). Ruimtelijke Ordening en Milieubeheer (2001). Nota ruimte. Available online at: https://www. ser. nl/~/media/db_adviezen/2000_2009/2004/b22768% 20pdf. ashx.
[487] Netherlands, S. (2022, January 18). Less pesticide used in agriculture. *Statistics Netherlands.* https://www.cbs.nl/en-gb/news/2022/02/less-pesticide-used-in-agriculture; Wedia. (n.d.). *Toxic chemicals threaten the quality of drinking water in the Netherlands*. IamExpat. https://www.iamexpat.nl/expat-info/dutch-expat-news/toxic-agricultural-chemicals-threaten-quality-drinking-water-netherlands. Last accessed 30 November 2023; *REPORT: Water sampling confirms "closed" greenhouses leak an alarming*. (2023, December 12). PAN Europe. https://www.pan-europe.info/press-releases/2023/12/report-water-sampling-confirms-%E2%80%9Cclosed%E2%80%9D-greenhouses-leak-alarming-number.

(PBL) indicated glyphosate as the main problem for extraction of drinking water.[488] Additionally, it was the most frequently occurring pesticide in the samples taken for the SPRINT studies of 2023.[489] This failure can also be evidenced by the high percentage of 63 % of urine samples from urban centers containing glyphosates.[490] Thus, a potential threat posed by glyphosate would remain a concern for all citizens and not just those actively handling products containing glyphosates.

Though the volume of glyphosate within the Netherlands is lower as compared to other EU nations, it is one of the highest as regards glyphosate per unit hectare of agricultural land.[491] The major share of this glyphosate use is flower and flower bulb cultivation whereas food crops are less reliant on glyphosate use.[492] Its use for the maintenance and upkeep of public areas and amenities such as railway tracks has almost been eliminated.[493] Thus, the reduction or banning of glyphosates would primarily have an impact on the flower trade. Another aspect to consider, as also pointed out in a scientific reflection to the House of Parliament, is that the current chemical or mechanical alternatives to glyphosate are not per se better.[494] A total and immediate ban might lead to the use of less inefficient chemicals- thus, resulting in more intensive usage and consequently, difficulties is meeting the emission reduction target.[495]

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[488] Wedia. (n.d.-b). *Toxic chemicals threaten the quality of drinking water in the Netherlands*. IamExpat. https://www.iamexpat.nl/expat-info/dutch-expat-news/toxic-agricultural-chemicals-threaten-quality-drinking-water-netherlands. Last accessed 30 November 2023.
[489] *170 verschillende bestrijdingsmiddelen aangetroffen in milieu, dieren en mensen in Nederland*. (n.d.). WUR. https://www.wur.nl/nl/nieuws/170-verschillende-bestrijdingsmiddelen-aangetroffen-in-milieu-dieren-en-mensen-in-nederland.htm Last accessed 30 November 2023.
[490] Determination of Glyphosate Residues in Human Urine Samples from 18 European Countries. 2018. https://www.foeeurope.org/weed-killer-glyphosate-found-human-urine-across-Europe-130613. Accessed 12 February 2021.
[491] Antier, C., Andersson, R., Auskalniene, O., Barić, K., & Simić, M. (2020). A survey on the uses of glyphosate in European countries. *ENDURE network*, 1-60.
[492] De Jong, F. M., De Snoo, G. R., & Loorij, T. P. (2001). Trends of pesticide use in The Netherlands. *Mededelingen (Rijksuniversiteit te Gent. Fakulteit van de Landbouwkundige en Toegepaste Biologische Wetenschappen)*, *66*(2b), 823–834.
[493] Kristoffersen, P., Rask, A. M., Grundy, A. C., Franzén, I., Kempenaar, C., Raisio, J., Schroeder, H., Spijker, J., Verschwele, A., & Zariņa, L. (2008). A review of pesticide policies and regulations for urban amenity areas in seven European countries. *Weed Research*, *48*(3), 201–214. https://doi.org/10.1111/j.1365-3180.2008.00619.x
[494] *Volledige ban op glyfosaat op korte termijn kan averechts uitpakken*. (n.d.). WUR. https://www.wur.nl/nl/nieuws/volledige-ban-op-glyfosaat-op-korte-termijn-kan-averechts-uitpakken.htm Last accessed 30 November 2023.
[495] De Wolf P., WUR/ Boerderij van de Toekomst (2023), Wetenschappelijke reflectie vanuit landbouwkundig perspectief Glyfosaat – een noodzakelijk kwaad? *Rondetafel Tweede Kamer 4-10-2023*.

6.2.4 Authorization of glyphosate

The Netherlands had approved the authorization of glyphosates at the EU level in 2017. However, there were limitations placed nationally on their use by non-professionals and in public areas, (as discussed in the earlier sections) even as they approved this authorization.[496] This stance is consistent with its overall pesticide policy, where it is sought to reduce risks posed by emissions and improper use.

The Cgtb, in its part, developed 2 assessment principles for all applications concerning glyphosate-based products.[497]Firstly, bearing in mind that the EU authorization was only for use as a herbicide, the Cgtb will deny all applications whose intended use is pre-harvest full field application for reasons such as uniform ripening of the crop.[498] Secondly, it established region-specific restrictive measures for the catchment area of the Meuse(as the glyphosate concentration levels in the drinking water extraction sites of these areas were seen to exceed the maximum residue limits).[499]Applications for intended glyphosate use closed and semi-open pavements in the catchment area of the Meuse would be denied.[500]

Within a year of this development, there were winds of change in the Dutch legislative body. In 2018, a majority of MPs voted in favor of a motion to no longer allow glyphosate in products for spraying grassland, green manure crops and catch crops.[501] This measure was determined to be legally untenable by reason of being in violation of EU rules.[502]

On the one hand Netherlands was the rapporteur for the glyphosate dossier for the reauthorization decision slated for 2022. On the other hand, concerns regarding its safety

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[496] Laylin, T. (2014, September 29). *The Netherlands says no to Monsanto bans roundup herbicide*. inhabitant.com. Retrieved November 30, 2023, from https://inhabitat.com/the-netherlands-says-no-to-monsanto-bans-roundup-herbicide/.
[497] *Glyfosaat*. (n.d.). WUR. https://www.wur.nl/nl/dossiers/dossier/glyfosaat-1.htm
[498] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2019, October 15). *Two principle decisions for glyphosate-containing products*. News Item | Board for the Authorisation of Plant Protection Products and Biocides. https://english.ctgb.nl/news/news/2019/10/15/principle-decisions-for-glyphosate-containing-products
[499] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2019, October 15). *Two principle decisions for glyphosate-containing products*. News Item | Board for the Authorisation of Plant Protection Products and Biocides. https://english.ctgb.nl/news/news/2019/10/15/principle-decisions-for-glyphosate-containing-products
[500] Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2019, October 15). *Two principle decisions for glyphosate-containing products*. News Item | Board for the Authorisation of Plant Protection Products and Biocides. https://english.ctgb.nl/news/news/2019/10/15/principle-decisions-for-glyphosate-containing-products
[501] Enter, M. (2022, October 11). *Glyphosate ban is possible - Resource online*. Resource Online. https://www.resource-online.nl/index.php/2022/10/10/glyphosate-ban-is-possible/?lang=en. Last accessed 30 November 2023.
[502] Enter, M. (2022, October 11). *Glyphosate ban is possible - Resource online*. Resource Online. https://www.resource-online.nl/index.php/2022/10/10/glyphosate-ban-is-possible/?lang=en. Last accessed 30 November 2023.

were gathering steam due to the various studies pointing out its high prevalence in Dutch food and water sources.[503] Further concerns about glyphosate's impacts on biodiversity and its link to neurological disorders, particularly Parkinsons disease were highlighted.[504] The houses of parliament received scientific and legal advice suggesting both approval and total bans.[505] Even those opposed to a total ban were , nevertheless, in favor of a gradual reduction of use of glyphosates and promoting research for alternative technology.[506] The legal tenability of deviating from the EU authorization was revisited-it was argued that the precautionary principle would allow for issuing restrictions or well-substantiated partial bans.[507]

In the run-up to the reauthorization decision, a letter signed by 291 scientists including 104 professors asking for the pesticide assessment framework to be reworked include learnings from independent science and base the glyphosate decision on this revised assessment.[508] The D66 party, part of the then coalition pushed for a partial ban.[509] Consequently, the Dutch farm Minister Adema declared the Dutch government's decision to abstain from the reauthorisation vote at the EU level.[510] This was sought to be an acknowledgement of both -

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[503] *170 verschillende bestrijdingsmiddelen aangetroffen in milieu, dieren en mensen in Nederland*. (n.d.). WUR. https://www.wur.nl/nl/nieuws/170-verschillende-bestrijdingsmiddelen-aangetroffen-in-milieu-dieren-en-mensen-in-nederland.htm Last accessed 30 November 2023; Determination of Glyphosate Residues in Human Urine Samples from 18 European Countries. 2018. https://www.foeeurope.org/weed-killer-glyphosate-found-human-urine-across-Europe-130613. Accessed 12 February 2021; Wedia. (n.d.). *Toxic chemicals threaten the quality of drinking water in the Netherlands*. IamExpat. https://www.iamexpat.nl/expat-info/dutch-expat-news/toxic-agricultural-chemicals-threaten-quality-drinking-water-netherlands. Last accessed 30 November 2023; *REPORT: Water sampling confirms "closed" greenhouses leak an alarming*. (2023, December 12). PAN Europe. https://www.pan-europe.info/press-releases/2023/12/report-water-sampling-confirms-%E2%80%9Cclosed%E2%80%9D-greenhouses-leak-alarming-number. Last accessed 30 November 2023.

[504] Van Der Gaag, B. L., Hepp, D. H., Hoff, J. I., Van Hilten, J., Darweesh, S. K., Bloem, B. R., & Van De Berg, W. D. (2023, September 8). *Risicofactoren voor de ziekte van Parkinson*. NTvG. https://www.ntvg.nl/artikelen/risicofactoren-voor-de-ziekte-van-parkinson. Last accessed 30 November 2023.

[505] Enter, M. (2023, October 12). *Five questions about glyphosate decision-making - Resource online*. Resource Online. https://www.resource-online.nl/index.php/2023/10/12/five-questions-about-glyphosate-decision-making/?lang=en. Last accessed 30 November 2023.

[506] De Wolf P., WUR/ Boerderij van de Toekomst (2023), Wetenschappelijke reflectie vanuit landbouwkundig perspectief Glyfosaat – een noodzakelijk kwaad? *Rondetafel Tweede Kamer 4-10-2023*.

[507] Schebesta, H. (2022). Juridisch onderzoek glyfosaathoudende gewasbeschermingsmiddelen. Wageningen Universty & Research.

[508] *Almost 300 scientists - 100+ profs - call on the government in*. (2023, November 15). PAN Europe. https://www.pan-europe.info/blog/almost-300-scientists-100-profs-call-government-belgium-and-netherlands-vote-no-glyphosate. Last accessed 30 November 2023.

[509] Wedia. (n.d.). *Toxic chemicals threaten the quality of drinking water in the Netherlands*. IamExpat. https://www.iamexpat.nl/expat-info/dutch-expat-news/toxic-agricultural-chemicals-threaten-quality-drinking-water-netherlands. Last accessed 30 November 2023.

[510] Pascoe, R. (2023, October 11). *Dutch commission research will abstain on EU pesticide vote - DutchNews.nl*. DutchNews.nl. https://www.dutchnews.nl/2023/10/dutch-commission-research-will-abstain-on-eu-pesticide-vote/. Last accessed 30 November 2023.

the outcome of the risk assessment by the EFSA and the concerns from society and the Dutch Parliament on the possible impact of glyphosate on biodiversity and human health.[511] Moreover, scientific research has been initiated at the National Institute of Public Health and the Environment (RIVM) on a possible causal link between the use of glyphosate and Parkinson's disease.[512] The Dutch government did not feel confident to grant approval that might not be able to be revoked easily before the results of the research by the RIVM were apparent.[513]

6.2.5 Role of precautionary principle

In this section, the questions identified earlier will be answered based on the discussion in the earlier sections:

- Is there is an explicit reliance on the precautionary principle in the decisions regarding authorization of glyphosate-based PPPs?

Neither the Ctgb nor the Dutch parliament rely explicitly on the precautionary principle. The precautionary principle was suggested as an argument to the Houses of Parliament for a potential ban on all glyphosate-based products in the Netherlands. However, neither did a total ban on glyphosate use transpire nor was the principle relied on for the control measures eventually instituted.

- Can the approach adopted to the possible threats posed by glyphosates be viewed as precautionary?

The Netherlands approved the authorization of glyphosate as an active ingredient in 2017, based off the EFSA and ECHA assessment. Thus, the decision did not adopt a precautionary approach at the time. The decision to abstain from voting for the reauthorization in 2022 was based on further concerns, different from those during the 2017 assessment, regarding the

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[511] Stöckl, B., & Mandilara, S. (2023, October 11). Dutch to abstain from voting on EU glyphosate renewal. *www.euractiv.com*. https://www.euractiv.com/section/politics/news/dutch-to-abstain-from-voting-on-eu-glyphosate-renewal/ Last accessed November 2023.
[512] Pascoe, R. (2023, October 11). *Dutch commission research will abstain on EU pesticide vote - DutchNews.nl*. DutchNews.nl. https://www.dutchnews.nl/2023/10/dutch-commission-research-will-abstain-on-eu-pesticide-vote/. Last accessed 30 November 2023.
[513] Pascoe, R. (2023, October 11). *Dutch commission research will abstain on EU pesticide vote - DutchNews.nl*. DutchNews.nl. https://www.dutchnews.nl/2023/10/dutch-commission-research-will-abstain-on-eu-pesticide-vote/. Last accessed 30 November 2023; Stöckl, B., & Mandilara, S. (2023, October 11). Dutch to abstain from voting on EU glyphosate renewal. *www.euractiv.com*. https://www.euractiv.com/section/politics/news/dutch-to-abstain-from-voting-on-eu-glyphosate-renewal/ Last accessed November 2023.

health hazards of glyphosate that has not been studied as yet. This decision can be termed precautionary as it chooses to delay authorization till the benign nature is sufficiently proven. Even so, it has not outright rejected the use of glyphosate but wishes to keep the discussion ongoing.

The approach adopted towards glyphosate use within the Netherlands by the Ctgb- reducing the admissible use cases, and region-specific restrictions are based on the assessments of regulations concerning specific subject areas where the risk has been ascertained. (Dutch national action plan on pesticides, water framework directive, limitations on use set forth in the authorization as active ingredient by the EU). Thus, these measures cannot be considered precautionary either. Even the reduction of glyphosate use as part of the over-arching policy of reducing pesticides emission cannot be seen as necessarily precautionary. The inherently toxic nature of pesticides and consequent maximum residue limits are the result of risk assessment frameworks without scientific uncertainty. The Dutch national action plan on pesticide use and the European Commissions' risk management reduction is consistent with this risk assessment.

- Has there been a change in the stance adopted by Member States at the EU level? Are there updates in current scientific knowledge or other triggers for such a change?

The measures to reduce reliance on glyphosates predated the authorization at the EU level and were part of a greater policy for reduction of pesticide residue in general. The approval vote at the EU level was not a departure from the existing policy towards pesticides or glyphosate in particular. Following the authorization decision at the EU level, only those control measures that would fulfil the limitations set forth in the EU risk management itself were introduced. Thus, again, the national measures restricting glyphosate use do not show a change in the stance of the Netherlands.

The decision to abstain from the vote for reauthorization in 2023 was a change from earlier decisions. This change in stance was adopted at the EU level itself and also supplemented by measures at the national level. Thus, though it is a change in approach towards glyphosates, it is uniform at the EU and national level. This change resulted from new credible scientific concerns relating to neurological disorders caused by glyphosates- a concern that had not been identified as yet and consequently, permissible levels of use and residue had not been adjusted to account for these dangers. Evidently, the change was the result of concerns raised by scientists.

- Is the precautionary approach towards glyphosates occasioned by the existing risk perception of pesticides in the country? Do the circumstances of that country explain a possible prioritization of risks posed by pesticides?

As discussed earlier, the Netherlands has not particularly displayed a precautionary approach towards glyphosates. Pesticides emissions have been a long -running problem for the country. In particular, it has posed a problem for drinking water production due to the geography and agricultural practices of the country. It is noteworthy that in spite of the negative experiences with pesticides and the heightened public opposition, the Dutch decision-makers did not adopt a precautionary stance towards glyphosates. The slightly precautionary approach came about when concerns were raised by a considerably large group of scientists.

- Does the composition and appointment of the decision-making body make it susceptible to public perception/industry influence?

The decision-making body for authorization of specific products in the Netherlands, the Ctgb, is primarily composed of subject experts and is independent of the political processes of the Government. Care has been taken to avoid conflicts of interest. The framework and acceptable thresholds that form the basis of the decisions are not within the powers of the Ctgb. Thus, a separation of responsibilities has been envisaged to make the decision-making more objective. The finances of the body rely on applications being made, irrespective of the decision and consultations to governmental bodies as also private actors at a fixed rate. Thus, susceptibility to public or industry opinion does not seem apparent nor is it evidenced in its decisions.

- Were both the benefits and threats considered in the assessment and how were they prioritized and addressed in the decision?

The benefits accrued by glyphosate use were considered not just in economic terms but also the environmental impact. The economic benefit was sought to be protected by placing restrictions mostly on non-professional use. Self-regulation and voluntary commitments were invited from those benefiting from the efficiency of glyphosate use professionally. Which chemicals would be used if glyphosates were banned and the quantities of these alternative chemicals that would be required and the consequent environmental impact was one of the considerations in deciding how gradually to reduce reliance on glyphosates. Stronger

restrictions were placed only in locations where the threat to drinking water was more acute-thus, prioritizing drinking water over efficiency for those farmers.

6.2.6 Conclusion

- ***Value addition by the precautionary principle***

In the Netherlands, the outcomes and regulations were based on existing risk assessment and management frameworks. In instances where the specific and more restrictive controls had to be instituted, they arose from the established framework. The flexibility to adapt the rules based on the circumstances of a region was granted within the framework itself. The possibility of a ban on glyphosates, legally tenable due to the precautionary principle, was not entertained. Even when a more cautionary stance against glyphosates was taken based on consultations with scientists, there was no explicit reliance on the precautionary principle and was explained by means of the prevalent risk analysis framework. As such, the precautionary principle itself had no role to play in the decision making or regulatory process in the Netherlands, even if cautionary decisions may have been taken.

- ***Criticisms of the precautionary principle***

It might be possible that even if it added no value to the process, the criticisms of the principle could, nevertheless, play a role. However, we cannot observe it to be the case in the Netherlands' approach to glyphosate use. In fact, it was more cognizant of scientific opinions than public perceptions and took into account a wider range of scientific opinions as opposed to just those selected by either side of the debate.

Rather than ignoring a risk/risk trade-off, the decision-making exhibits a more expansive consideration of the trade-offs. It acknowledges that an action intending to protect from a specific potential threat to human health could itself be detrimental in other ways-not just for economic efficiency but for environmental protection as well.

Neither was over-regulation of glyphosate use occasioned by the strong public opposition to it. The restrictions placed on glyphosate use were clearly defined and limited. Consequently, there would not arise the need to append never-ending proof for authorization applications. Simultaneously, an impetus was given for further innovation in alternative integrated pest management and targeted weed control technology.

Furthermore, both the Dutch national executive and the decision-making agency Ctgb, were extremely mindful of their jurisdictional competencies and permissible actions. It might even be said that the Dutch national executive might have been over-cautious in not wanting to violate the EU decisions- where it chose to stick strictly to the authorization of glyphosate even when presented with a legally tenable justification for deviations in certain circumstances.

Considering the above discussion, the precautionary principle seems to have played almost no role, positive or negative, in the Dutch response to the uncertain threat posed by glyphosates. Nevertheless, cognizance of the potential threat has been taken and establishing path dependencies has been avoided in the Dutch response

6.3 Germany

6.3.1 Regulatory regime governing the authorization and use of plant protection products

In Germany, the review of active substances in plant protection products falls within the remit of two separate agencies. The Federal Institute for Risk Assessment (BfR) is entrusted with the scientific risk assessment of plant protection products and their active substances. [514]The assessment of the BfR and its advice regarding risk management options forms the basis for decisions by the Federal Office for Consumer Protection and Food Safety (BVL).[515] The Plant Protection Department within the BVL is responsible for assessing and establishing Maximum Residue Limits (MRLs) and risk management decisions related to plant protection products, strengtheners, and adjuvants. [516] Thus, the authorization for use of plant protection products is issued by the BVL, albeit relying on assessments by the BfR.

Both the BVL and the BfR were set up in 2002 in response to the discussion resulting from the BSE (Bovine Sponge Encephalopathy/ Mad Cow disease) crisis in 2000.[517] A need was felt for strengthening consumer protection and better coordination of food safety between federal government, federal states, and the European Union. Based on an official report by the Commissioner for Administrative Efficiency, new organisations were established to address

[514]Plant Protection Act of February 6, 2012 (BGBl. I p. 148, 128), Section 11.
[515]Plant Protection Act of February 6, 2012 (BGBl. I p. 148, 128), Section 11.
[516]Plant Protection Act of February 6, 2012 (BGBl. I p. 148, 128), Section 11.
[517] Law on the Establishment of a Federal Office for Consumer Protection and Food Safety (BVL Law - BVLG)

consumer health concerns.[518] To improve transparency of government actions, risks concerning consumer health protection were to be evaluated and managed by different institutions.[519]

- ***Federal Institute for Risk Assessment (BfR)***

The BfR conducts risk assessment as per the procedure specified in EU Regulation (EC) No 1107/2009 and the German Plant Protection act.[520] The authorization of a plant protection product requires that, when the product is used correctly and in line with its intended purpose, the protection of the health of all groups of people who may come into contact with the pesticide, or its residues is ensured.[521] To this end, toxicological effects must be identified and quantified. Additionally, the exposure of each group of people who may encounter the product must be estimated. The risk of a product is determined by comparing the toxic effect with the estimated exposure while considering means of reducing exposure. The scope of the assessment extends to a toxicological assessment to determine the risk as well as suggesting classification and labelling of the product and safety instructions for users as well as those indirectly affected.[522]

The Bfr uses a network of 21 National Reference Laboratories and a permanent staff of scientists for the assessments. Presently, 534 scientists are employed in its 13 commissions.[523] The scientists employed are civil servants and as a result, must comply with all federal laws[524] pertaining to transparency, anti-corruption and declaration of conflicts of interests.[525]Consultations are conducted with various stakeholders (NGOs, manufacturers, users, residents near agricultural areas) in the process of risk assessment.[526] However, these consultations are for the reference of the assessors and do not have to be necessarily relied

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[518] Hedda von Weddel, *Organisation des gesundheitlichen Verbraucherschutzes Schwerpunkt Lebensmittel,* (Schriftenreihe der Bundesbeauftragten für Wirtschaftlichkeit in der Verwaltung; Bd. 8) 8 February 2001.
[519]Hedda von Weddel, *Organisation des gesundheitlichen Verbraucherschutzes Schwerpunkt Lebensmittel,* (Schriftenreihe der Bundesbeauftragten für Wirtschaftlichkeit in der Verwaltung; Bd. 8) 8 February 2001.
[520]Plant Protection Act of February 6, 2012 (BGBl. I p. 148, 128.)
[521]Plant Protection Act of February 6, 2012 (BGBl. I p. 148, 128) Sec.35.
[522]Plant Protection Act of February 6, 2012 (BGBl. I p. 148, 128), Sec. 31 –36.
[523]Facts and Figures page, Website for Bundesinstitut für Risikobewertung. Available at: https://www.bfr.bund.de/en/facts_und_figures-54273.html#Humanresources. Last accessed 10 May 2022.
[524] German Civil Service Act, Art. 10; Administrative Procedures Act.
[525]*Questions and Answers on Ensuring the Independence of the Federal Institute for Risk Assessment (BfR),* Bundesamt fur Risikobewertung, 30 May 2012. Available at: https://www.bfr.bund.de/cm/349/questions-and-answers-on-ensuring-the-independence-of-the-federal-institute-for-risk-assessment.pdf
[526]German Federal Institute for Risk Assessment. Federal Institute for Risk Assessment (bfr) - Guidance Document for Health Assessments. *Zenodo*, 1 Nov. 2007, p., doi:10.5281/zenodo.580937.

upon.[527] All spare-time work or parallel secondary employment needs be checked in advance to be compliant with the German Civil Service Act. [528] As such, the assessors are prevented from working for industry in their spare time. The BfR received a budget of €119 million for its statutory tasks and €6.7 million from third party funding.[529]

- ***Federal Office for Consumer Protection and Food Safety (BVL)***

During the new organisation in 2002, the Plant Protection Product operating under the Biological Federal Institute for Agriculture was transposed into the new federal authority formed for consumer health risk decisions. The risk management decisions related to plant protection products and consequently, their authorization is within the remit of the BVL. Additionally, it can undertake administrative measures for protection of humans and animals.

The BVL explicitly recognises one of its challenging objectives as being to replace reaction with prevention.[530] In making risk management decisions, it places value on being able to reach effective countermeasures quickly before a crisis emerges, whilst balancing competing objectives.[531]

As part of the available measures, it can specify details as to toxicity or safety measures to be included as also the manner in which they are to be shown on the labels.[532]

6.3.2 Pesticide Policy

The use and marketing of pesticides in Germany is regulated by the Plant Protection Act along with various ordinances and amendments attached to it. The Act is based on the EU regulation as regards risk assessment templates and authorisation of plant protection products. It further goes on to specify credentials and requirements for pesticide users and equipment for spraying, set up alert systems for reporting frequency of use and monitoring illegal trade.[533] The current legislation on pesticides explicitly recognises the application of the precautionary principle for

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[527]German Federal Institute for Risk Assessment. Federal Institute for Risk Assessment (bfr) - Guidance Document for Health Assessments. *Zenodo*, 1 Nov. 2007, p., doi:10.5281/zenodo.580937.

[528]*Questions and Answers on Ensuring the Independence of the Federal Institute for Risk Assessment (BfR),* Bundesamt fur Risikobewertung, 30 May 2012. Available at: https://www.bfr.bund.de/cm/349/questions-and-answers-on-ensuring-the-independence-of-the-federal-institute-for-risk-assessment.pdf

[529] Facts and Figures page, Website for Bundesinstitut für Risikobewertung. Available at: https://www.bfr.bund.de/en/facts_und_figures-54273.html#Humanresources. Last accessed 10 May 2022.

[530]*Statement of Objectives*, Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit. Available at: https://www.bvl.bund.de/EN/FederalOffice/03_Objectives/Objectives_node.html?cms_thema=Objectives. Last accessed 10 May 2022.

[531]Ibid.

[532] Plant Protection Act of February 6, 2012 (BGBl. I p. 148, 128) Section 31, 43, 47.

[533] Ordinance on plant protection products and tools used in plant protection of 9 March 2005(BGBl. I n.53 p.2161-2169)

the purposes of ensuring a high level of protection of human and animal health as also the environment.[534] At the same time, it acknowledges the objectives of maintaining food security and competitiveness of agriculture.

The national policy towards pesticide use has been shaped by the National Action Plan on pesticide[535] implemented in 2005. The National Plan was the result of a conference of about 60 representatives from the plant protection industries, farmer's collectives, civil society organisations and organic farming advocates.[536] Prior to 2000, Germany had taken no concrete stance towards reducing pesticide use even as many other EU nations were doing so.[537] In fact, pesticide use in Germany had increased significantly in the 90's decade.[538] Following the EU committing to pesticide reduction as one of its sustainability goals[539] coupled with human health crises caused by pesticide residues in food, the conference was convened to discuss a pesticide use policy going forward.[540]

The primary bone of contention in the conference was as regards setting quantitative v qualitative goals.[541] The preference for one or the other is explained by the underlying risk perception of pesticides. Those pushing for quantitative goals believed there persists an uncertainty about the consequences of pesticide use.[542] As such, it would be better to reduce overall pesticide use and work towards transitioning to agricultural techniques that are less reliant on it. On the other hand, those suggesting qualitative goals were of the opinion that risks related to pesticides can be assessed and accordingly controlled.[543] In effect, problems would arise from improper or illegal pesticide use and the efforts should be towards controlling and monitoring the proper use and application of pesticides. Additionally, there would be a focus on recording frequency of use, particularly near water sources or urban areas.

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[534]Plant Protection Act of February 6, 2012 (BGBl. I p. 148, 128), Sec.1.
[535]Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft, 2005. Reduktion Programm chemischer Pflanzenschutz. Berlin.
[536]Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA), Beiträge der Biologischen Bundesanstalt für Land- und Forstwirtschaft zum Reduktionsprogramm chemischer Pflanzenschutz, 2005 http://www.bba.de/mitteil/aktuelles/forumpfs/beitraege_bba.pdf
[537]Germany, Pesticide Action Network. "Towards Pesticide Use Reduction in Germany." (2005), 45.
[538]Germany, Pesticide Action Network. "Towards Pesticide Use Reduction in Germany." (2005), 45.
[539]European Commission (EC), Environment 2010: Our future, our choice - The Sixth Environmental Action Programme, COM (2001)31, Brussels 2002, http://europa.eu.int/comm/environment/newprg/
[540] SPD, Bündnis 90/DIE GRÜNEN, Koalitionsvertrag 2002 - 2006: Erneuerung - Gerechtigkeit – Nachhaltigkeit, Berlin 2001
[541]Germany, Pesticide Action Network. "Towards Pesticide Use Reduction in Germany." (2005), 47-48
[542]Germany, Pesticide Action Network. "Towards Pesticide Use Reduction in Germany." (2005), 48.
[543]Germany, Pesticide Action Network. "Towards Pesticide Use Reduction in Germany." (2005), 49.

Ultimately, the National Plan adopted more of the suggested qualitative goals. Though it was stated that pesticide use should be limited to only 'necessary extent' no specific target in terms of use reduction, or a deadline were set forth.[544] What constitutes 'necessary extent' was also not clearly defined.[545] The National Plan particularly focusses on the protection of water sources, groundwater as well as terrestrial, and ecosystems. Thus, more measures relate to setting up buffer zones near water sources, immediate reporting of contamination of a water source and controlling use of pesticides in urban areas. Another area of concern seems to be accumulation of residue in food, particularly that consumed by younger age groups.[546] Multiple studies and surveys to assess the levels of residues in children's meals have been undertaken.[547] A rapid alert system between the federal states has been established to quickly communicate risks that may be observed in any region or foodstuff. Furthermore, detailed procedures for qualification, training and certification of personnel handling pesticides have been set forth.[548] A major investment has been the setting up of a taskforce to combat illegal trade in pesticides- either not approved for the German markets or sale to unauthorized personnel.[549] There is some investment in developing Integrated Pest Management techniques which would reduce the necessity of pesticides through purposeful crop rotation and other organic measures.[550] However, currently there are no financial incentives for farmers to shift to such a method.

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[544]Kristoffersen, P., et al. "A review of pesticide policies and regulations for urban amenity areas in seven European countries." *Weed Research* 48.3 (2008): 201-214; Germany, Pesticide Action Network. "Towards Pesticide Use Reduction in Germany." (2005), 47-48.

[545]Bürger, Jana, Friederike de Mol, and Bärbel Gerowitt. "The "necessary extent" of pesticide use—thoughts about a key term in German pesticide policy." *Crop Protection* 27.3-5 (2008): 343-351.

[546] *Special rapporteur on right to food- questionnaire to prepare annual report on the implications of the use of pesticides on the right to food Germany response*, Permanent Mission of the Federal republic of Germany to the Office of the United Nations,30 November 2016.

[547] BfR MEAL Study (**M**ahlzeiten für die **E**xpositionsschätzung und **A**nalytik von **L**ebensmitteln – "meals for exposure assessment and analysis of foods"); "KiESEL study", which stands for "**Ki**nder-**E**rnährungs**s**tudie zur **E**rfassung des **L**ebensmittelverzehrs" (The Children's Nutrition Survey to Record Food Consumption); ELS study (Consumption study to determine the food intake of infants and young children for the estimation of an acute toxicity risk from pesticide residues, „Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von Pflanzenschutzmitteln"), 2002.

[548]Ordinance on plant protection products and tools used in plant protection of 9 March 2005(BGBl. I n.53 p.2161-2169)

[549]*Special rapporteur on right to food- questionnaire to prepare annual report on the implications of the use of pesticides on the right to food Germany response*, Permanent Mission of the Federal republic of Germany to the Office of the United Nations,30 November 2016, 2; Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft, 2005. Reduktion Programm chemischer Pflanzenschutz. Berlin.

[550]Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft, 2005. Reduktion Programm chemischer Pflanzenschutz. Berlin.*Ibid.*

Neither are there financial disincentives in using pesticides, such as additional taxes which had been suggested in the conference.[551]

Considering the above discussion, it appears that German pesticide policy is not strongly in favour of pesticide reduction as a goal in itself. It is geared more towards containing the associated risks through safety measures, limiting the areas of application, monitoring the frequency of use and quicker risk communication.

6.3.3 Consideration of Risk vs Benefit

Germany views the threat posed by pesticides as affecting humans indirectly through water or food contamination rather than direct exposure causing health complications. It also acknowledges the risk to ecosystems and their functioning due to reduced populations of various species resulting from uncontrolled pesticide use. Thus, though pesticides have been determined as risky, the nature of the risk has been characterised as manageable through strict safety measures and limited frequency of use.

On the other hand, it has recognised pesticide use as an important component of internal food security and safeguarding the right to food.[552] Even in the objectives of the Plant Protection Products Act, the necessity to balance application of precaution against maintaining food security and agricultural competitiveness has been highlighted.[553]

6.3.4 Authorization of glyphosates

Germany's position on glyphosates, before and after the approval of glyphosates, has been followed with interest within the EU seeing as it was the decisive vote in renewing approval for glyphosates. The BfR was the rapporteur for the renewal process of glyphosates initiated in 2015. The European Food Safety Authority relied on the reports submitted by the BfR in reaching its conclusion that glyphosates pose no risk to humans.

Even so, Germany abstained in the vote for a 10-year renewal of glyphosate authorization. It was understood as the compromise between the CDU's stance of not being averse to the approval and staunch opposition by the SDP. Their opposition to glyphosates was based on the IARC's findings of possible carcinogenicity.

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[551] Germany, Pesticide Action Network. "Towards Pesticide Use Reduction in Germany." (2005), p.51.

[552] *Special rapporteur on right to food- questionnaire to prepare annual report on the implications of the use of pesticides on the right to food Germany response*, Permanent Mission of the Federal republic of Germany to the Office of the United Nations,30 November 2016, p.1; Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft, 2005. Reduktion Programm chemischer Pflanzenschutz. Berlin.

[553] Plant Protection Act of February 6, 2012 (BGBl. I p. 148, 128), Sec.1.

As the decision on glyphosate approval continued to be delayed at the EU level, new information kept emerging in Germany to further increase opposition to glyphosates. Bayer acquired Monsanto in 2016 and was immediately embroiled in civil lawsuits relating to Round Up in the US courts. Bayer was held liable to a compensation amount of $2.424 billion.[554] During the course of these lawsuits, certain papers known as 'Monsanto Papers' came to light revealing malpractices by Monsanto aimed at hiding concerns linking glyphosate to cancer.[555]These developments were reported in German newspapers and opposition to glyphosate increased amongst the public. Additionally, concerns arose about the transparency and the credibility of the report prepared by the BfR due to 2 reasons. Firstly, it was reported that major portions of the reports were plagiarised from industry-funded studies, particularly the Monsanto papers.[556] Secondly, news surfaced about the Laboratory of Pharmacology and Toxicology (LPT) in Hamburg having falsified records in certain other cases.[557] Opposers of glyphosates questioned the BfR 's glyphosate reports pointing to the fact that 7 of the studies relied on by the BfR in the glyphosate reports were done by the discredited LPT laboratory.

In the following rounds of voting, Germany abstained right till October 2017 even as the approval period was reduced to 5 years. However, a month later, glyphosate use was approved for 5 years in the EU as a result of Germany voting in favour of the decision. Further questioning of why the change occurred led to the German agriculture minister admitting that he acted individually though the Chancellor and the coalition of parties had agreed otherwise.[558]

However, the German government sought to correct this aberration by announcing a plan to systematically phase out the use of glyphosates by the end of 2023.[559] Following a strong tussle between the environment and agriculture ministers, draft legislation to this effect was

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[554] Ludwig Berger, Tina Bellon, *Bayer to pay up to $10.9 billion to settle bulk of Roundup weedkiller cancer lawsuits,* Reuters, 24 June 2020. Available at: https://www.reuters.com/article/us-bayer-litigation-settlement-idUSKBN23V2NP. Last accessed 10 May 2022.

[555]McHenry, Leemon B. "The Monsanto Papers: poisoning the scientific well." *International Journal of Risk & Safety in Medicine* 29.3-4 (2018): 193-205.

[556]McHenry, Leemon B. "The Monsanto Papers: poisoning the scientific well." *International Journal of Risk & Safety in Medicine* 29.3-4 (2018): 193-205.

[557] Corporate Europe Observatory, PAN Germany and GLOBAL 2000, "Dangerous Confidence in 'Good Laboratory Practice'" (Corporate Europe Observatory, PAN Germany, and GLOBAL 2000, 2020) <https://www.global2000.at/sites/global/files/2020-GoodLaboratoryPractice-en.pdf>.

[558] Judith Mischke and Ginger Hervey, *Germany's Christian Schmidt admits taking glyphosate decision alone,* Politico, 28 November 2017. Available at: https://www.politico.eu/article/christian-schmidt-germany-admits-taking-glyphosate-decision-alone/ Last accessed 10 May 2022.

[559]Maria Sheahan, *German cabinet approves legislation to ban glyphosate from 2024,* Reuters, 10 February 2021. Available at: https://www.reuters.com/article/us-germany-farming-lawmaking-idUSKBN2AA1GF. Last accessed 10 May 2022.

introduced in September 2019.[560] It is noteworthy that the objective of this phase out has been stated to be the protection of insects. Thus, it does not cite the possible carcinogenicity as a reason to reduce glyphosate use. As an initial limitation, use of glyphosate was banned in city parks and private gardens. It was further intended to restrict its use in species-rich environments such as grasslands, orchards and along river and lake shores.

The proposed ban has garnered backlash from farmer's groups as well as the Chemical Industry Association.[561] The plant protection product manufacturers point to such a ban being opposed to the position taken by the EU and thus threatening confrontation with European Law. Farmer 's groups are disgruntled with the negative representations of the agricultural industry and additional burden of operating without support to transition from glyphosates.

A particular development of note within Germany occurred in Bavaria in February 2019- a referendum regarding glyphosate in particular and pesticides in general was held amidst opposing campaigns of 'save the bees' and 'stop bashing farmers'[562]. A record 1.75 million people voted to phase out pesticides and move towards more organic ways of farming. The State government stated its intention to convert the referendum into government policy.

Thus, though Germany voted for approval of glyphosate at the EU level, its response towards its use has been less than welcome before and after the approval process. At the same time, the reduction in use is presently not affecting agricultural application.

6.3.5 Role of the Precautionary Principle

In this section, the questions identified earlier will be answered based on the discussion in the earlier sections:

- Is there an explicit reliance on the precautionary principle in the decisions regarding authorization of glyphosate-based PPPs?

There was no explicit reliance on the precautionary principle in reaching decisions regarding authorization of glyphosates at either the EU level or the national level. Indeed, the precautionary stance at the EU Level decision was triggered by the divergent scientific

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[560]Maria Sheahan, *German cabinet approves legislation to ban glyphosate from 2024,* Reuters, 10 February 2021. Available at: https://www.reuters.com/article/us-germany-farming-lawmaking-idUSKBN2AA1GF. Last accessed 10 May 2022.

[561]Ibid.

[562]Robert Kunzig, *Bavarians vote to save bugs and birds—and change farming,* National Geographic, 13 February 2019. Available at: https://www.nationalgeographic.com/environment/article/bavarians-vote-save-bugs-birds-change-farming Last accessed 10 May 2020.

findings as to possible carcinogenicity of glyphosates. However, the stronger opposition to glyphosates resulted from issues as to transparency of the assessments of plant protection products. Indeed, this opposition would highlight the role of the precautionary principle as a regulatory process. Nevertheless, there was no explicit reliance on this aspect of the principle either.

The ultimate approval at the EU level was the exercise of individual discretion by the then German agricultural minister. It must be noted that this discretion did not take a precautionary stance against the potential threat. The resulting backlash to this unilateral decision, however, did push the German government to appear to take corrective measures, *viz,* the consequent introduction of legislation to phase out glyphosates. However, this legislation, also did not rely explicitly on the precautionary principle.

- Can the approach adopted to the possible threats posed by glyphosates be viewed as precautionary?

The German legislature has passed a law to phase out the use of glyphosates by 2023. Thus, the response to the possible threats is indeed of a precautionary nature. However, the ban on glyphosates was not immediate and neither is it affecting agricultural application currently. Market authorizations for PPPs with glyphosate as their active ingredient have been granted, Thus, it is not a strong precautionary approach to the potential threat. Even so, the proposed plan is much more precautionary towards the glyphosate threat than it has been to any other pesticide-related threat in Germany.

- Has there been a change in the stance adopted by Member States at the EU level? Are there updates in current scientific knowledge or other triggers for such a change?

Germany approved authorization for glyphosates at the EU level but then proceeded to pass legislation planning a phase out within its territory. It appears that there has been a change in the stance adopted at the EU level and the national level. However, it must be noted that the approval at the EU level was later admitted as being a unilateral decision of one minister and not representative of the German federal government. Thus, the stance opposed to glyphosates has not actually changed. However, the opposition was definitely strengthened due to this minister's action. The opposition to glyphosates was then stronger based off transparency and accountability concerns rather than changes in scientific knowledge.

- Is the precautionary approach towards glyphosates occasioned by the existing risk perception of pesticides in the particular country?

The present pesticide policy of Germany regards risks posed by pesticides to be arising from improper use rather than an inherent risk that cannot be controlled fully. It does not have quantitative reduction goals. The pesticide regulations focus on certifications for users, better equipment for application and setting up a quick monitoring and alert system in case of a contamination. Thus, the phase out of glyphosates is not consistent with this risk perception of pesticides. The legislation banning glyphosates treats their potential threat as uncontrollable through safety measures. The systematic and gradual phase out rather than an immediate ban is to facilitate a transition without burdening the agricultural industry. Thus, the precautionary approach towards glyphosates, albeit staggered, is a departure from the existing risk perception of the country.

- What are the particular circumstances of that country explaining a possible prioritization of risks posed by pesticides?

As such, the risks posed by pesticides were not prioritised till a human health crisis related to pesticide contamination of food occurred. Understandably, following such a crisis, these risks were prioritized. Even so, the regulatory response was to the extent of monitoring proper use of pesticides and setting up alert systems for contamination cases. Even though guidelines for using pesticide to the necessary extent were made, concrete goals for reduction of pesticide use were not established. Pesticides continued to be recognized as an important tool for achieving food security and agricultural competitiveness. Thus, it could be concluded that the risks posed by pesticides were not prioritized in the national policy over the benefits that pesticides accrued.

- Were both the benefits and threats considered in the assessment and how were they prioritized and addressed in the decision regarding glyphosates?

The national action plan on sustainable pesticide use in Germany has acknowledged the role of pesticides in achieving food security and maintaining agricultural competitiveness. The measures in the national action plan do not ask for a reduction in pesticide use, regardless of the costs of transitioning to alternative techniques. Rather, the focus is more on certification

and training for better use, identifying particularly vulnerable locations and populations and better equipment for spraying to reduce exposure. Thus, the national action plan attempts to put forth measures balancing the benefits and threats related to pesticides.
However, the decision regarding glyphosates cannot be seen to be in the same vein. The legislation is ultimately aiming to ban glyphosate use altogether. Thus, the potential threat is being regarded greater than the current benefits accrued from glyphosates. The regulation does acknowledge the benefits as also the problems associated with moving away immediately form glyphosates. Accordingly, it sets out a staggered phase out of the potentially harmful substance as also investing in research and deployment of alternative techniques. Thus, the benefits have not been ignored in formulating the legislation banning glyphosates.

- Does the composition and appointment of the decision-making body make it susceptible to public perception/industry influence?

The responsibility of market authorization for PPPs has been divided between two federal institutions. The members of these institutions are appointed in compliance with regulations aimed at avoiding conflicts of interest and promoting accountability. Thus, the decision-making body in itself does not depend on the public perceptions of its decisions for continued appointment or operation. On the other hand, the strong opposition towards glyphosates in this case was more so strengthened due to a lack of transparency in the research institutions these decision-making body relies on. Thus, the working of the decision-making body was seen as being indirectly impacted by industry influence. Consequently, public perception towards the potential threat was shaped, which ultimately affected the decision of the legislature. Thus, though the composition and appointment of the agency responsible for PPP authorization does not make it particularly vulnerable to public or industry influence, the decisions in this case, nevertheless, appear to be impacted by both.

6.3.6 Conclusion

- ***Value addition of the precautionary principle***

The precautionary stance adopted by Germany was not occasioned by the operation of the precautionary principle as a decision-making rule. As the stance was in response to public concerns of transparency in the assessment, it may appear that the precautionary principle as a regulatory process was operational. However, the response did not result in changes to the

regulatory process to ensure greater transparency and accountability for future assessments. It only addressed the potential threat of glyphosates.

- ***Criticisms of the precautionary principle***

The agency responsible for authorizations has not adopted a precautionary stance. The legislature's precautionary approach has been occasioned by the public perception of the potential threat. This perception has been shaped more so due to concerns regarding transparency and credibility of governmental risk assessments. Thus, it could be said that the criticism that the precautionary principle makes decision-making bodies susceptible to risk-averse public sentiment can be seen in this case. Considering the German pesticide policy hitherto, a potential threat posed by glyphosate would have been countered with greater safety measures and monitoring frequency of use. A ban, even if staggered, is a deviation from this policy and suggests that it was influenced by public opinion and not the prevalent scientific opinion.

Even so, the legislature's thusly influenced decision calls for a staggered reduction and investments in alternative techniques. Consequently, the risk/risk trade-off has not been ignored in formulating the legislation. Lastly, there have as yet been no instances of regulatory overreach to counter the potential threat posed by glyphosates.

6.4 Comparison of case -studies

6.4.1 Explicit reliance on the precautionary principle

Among the three countries, there has been an explicit reliance on the precautionary principle only in the singular instance of a judicial decision in France. Thus, even in France, the regulatory body itself did not invoke the precautionary principle for its decisions. This implies that the decision-making regarding glyphosate did not rely explicitly on the precautionary principle. This is conspicuous considering the regulations in all the three countries do provide for the precautionary principle as a guiding principle for authorization of plant protection products. Moreover, in the cases of France and the Netherlands, the possibility of invoking the precautionary principle was also made salient- by way of the judiciary and legal advice submitted to the House of Parliament respectively. Even so, none of the countries chose to cite the precautionary principle as the basis for any action they might have taken.

6.4.2 Influence of the precautionary principle

Even in the absence of an explicit reliance on the precautionary principle, precautionary measures against glyphosates were adopted in all the three countries. Of these, the measures within the Netherlands remained consistent with the existing pesticide policy and risk analysis framework – as such there was no addition or deviation caused by the precautionary principle. Even in France, though the measures were more precautionary than those in the other two countries, they remained in line with the existing pesticide policy and risk perception of pesticides prevalent in France. The only noticeable influence of the precautionary principle was seen in the French regulatory agency's communication regarding the requirements of proof for future authorization applications for glyphosate-based products. In Germany, the measures to curtail glyphosate use were a clear departure from the norm, and more precautionary than those applied to other pesticides. The reason for these measures, rather than greater concern about the potential threat posed specifically by glyphosates, were the transparency and integrity concerns surrounding the assessment within Germany and its vote at the EU level. However, the precautionary principle did not work to make the assessment process itself more transparent or inclusive- the change was only for reduction of glyphosate use. Thus, in all three cases, the triggers for the precautionary measures or deviations from established processes were either the prevalent pesticide policy or public concern over the integrity of the regulatory agencies- and not an application of the precautionary principle.

6.4.3 Consistency with EU level decision

France and Netherlands have remained consistent with their stance adopted at the EU level in the measures they chose to adopt nationally as well. Indeed, the Netherlands refused the idea of even a staggered ban on glyphosate-use as it would be a violation of the decision reached at the EU and would be against the approving stance they had adopted there. France continued with measures in line with their already established pesticide policy and rejection of glyphosate use at the EU level. However, Germany exhibited inconsistency not only from the stance at the EU level but also its from its own pesticide policy. This seems to be the result of both decisions – at the EU level and within the country -not having any basis in the established risk analysis framework. It was therefore not the attitude to risk of the population that caused the excessive political discretion or the inconsistent measures that were taken in Germany. It was rather a concern with respect to transparency (more particularly the intervention of the minister at EU level) that led to the observed inconsistencies.

6.4.4 Criticisms of the precautionary principle

The apparent divergence in scientific opinion coupled with concerns relating to transparency in the process may have caused the uncertain threat to be viewed as more dangerous than suggested by scientific reporting. This greater risk-aversion caused by an uncertain threat is consistent with criticisms of the precautionary principle put forth by its opponents.[563] However, the consequences of neglecting a risk/risk trade-off and a risk averse bureaucracy arising from this exaggerated view of the uncertain threat outlined in their criticisms cannot be seen to have occurred.

In all instances, precautionary measures have been cognizant of their impact on food supply chains and agricultural trade. In fact, the Netherlands also considered the environmental impact of glyphosate- alternatives as well. As a result, the measures in the Netherlands aimed at a staggered reduction of glyphosate use whilst simultaneously investing substantially in research on alternatives and supporting the transition to these alternatives. Thus, even if there may be an exaggerated view of the threat in the public, it has not affected administrative decisions to ignore the risk/risk trade-off. These decisions remain informed by all available scientific data and a balancing of different interests. Rather than stagnate innovation, it has resulted in opening up new avenues of research.

However, there is not a complete absence of shortcomings resulting from the precautionary principle. The principle was relied on by different local municipal units in France to attempt to institute measures beyond their competencies. Considering these over-reaching measures garnered support from a majority of the citizens affected by it, the principle does seem to enable regulatory over-reach. However, this is observed at only the municipal level. Eventually, the measures were contested by either a higher administrative unit or a minority group and struck down by the judiciary for constitutional reasons, unrelated to the application of the precautionary principle. In the Netherlands, the national regulatory agency strove to fastidiously stick to its assigned competency, despite public outrage. Thus, the trust-enhancing mechanism and consequent regulatory over-reach seems to be enabled more at the local governance level rather than nationally.

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[563] Adler, J. H. (2011). The problems with precaution: A principle without principle; Majone, G. (2002). The precautionary principle and its policy implications. JCMS: Journal of Common Market Studies, 40(1), 89-109; Sunstein, C. R. (2005). Laws of fear: Beyond the precautionary principle (Vol. 6). Cambridge University Press, 7.

Chapter 7: Conclusion

7.1 Introduction

The thesis has been a positive analysis of the role of the precautionary principle within the EU in decisions regarding uncertain threats within the EU. The authorization of glyphosate use within the EU was analyzed to understand the role played by the precautionary principle. This decision lent itself as an appropriate case -study due to two reasons. Firstly, it was a suitable case for the application of the precautionary principle based on the EU Communication about the precautionary principle.[564] Namely, there existed substantial divergence in scientific opinions as regards the threat of potential carcinogenicity for humans posed by glyphosate exposure.[565]Secondly, the EU regulations for pesticide authorization require decisions to be made by the European Commission as well as by national governments for regulations within their territories.[566] Thus, the role of the precautionary principle and whether it changes at supra-national and national levels of administration could be studied.

This concluding chapter shall firstly briefly set up the background of the research and summarize the reasoning for the research questions. Secondly, it shall answer these research questions based on the observations and analysis of the earlier chapters. Lastly, it shall articulate the implications and relevance of these answers and the analysis and put forth suggestions for further areas of enquiry.

7.2 Summary

7.2.1 Background

- ***Definition and standing of the precautionary principle***

At its core, the objective of the precautionary principle was to minimize avoidable harm to the environment and human health through anticipatory or preventative regulatory

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[564] Science for Environment Policy (2017) The Precautionary Principle: decision making under uncertainty. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol. Available at: http://ec.europa.eu/science-environment-policy.
[565] International Agency for Research on Cancer (2015). *Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos. Glyphosate Lyon: IARC. 1–92.*
[566] Regulation (EC) No 1107/2009, Art.7 and Art.33.

controls.[567] In order to achieve this, it allows for the restriction of activities or technologies whose environmental consequences are potentially serious till uncertainty as regards these consequences is resolved.[568]

The precautionary principle in environmental law was formally articulated as such for the first time in the Rio Declaration of 1992.[569] To this date, it continues to be the most widely used definition of the principle and provides the basic tenets for all other formulations of the principle, *viz* existence of uncertainty regarding serious threat to human health or the environment and the allowing for regulatory action to limit the impact of the uncertain threat. The degrees of seriousness and extent of the regulatory action change in the various formulations.

Within the European Union, the definition used has been given in the European Union's Communication on the Precautionary Principle (2000)[570] as "The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU." Recourse to the principle belongs in the general framework of risk analysis (which, besides risk evaluation, includes risk management and risk communication), and more particularly in the context of risk management which corresponds to the decision-making phase.[571] However, certain EU legislations also make a further explicit mention of requiring consistency with the principle.

- ***Intended value-addition***

The precautionary principle was intended primarily as a tool to help decision-making in case of uncertainty, recognizing the inadequacy of purely numerical methods for risk-management.[572] Over the years, it has operated as a higher order principle, which calls for

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[567] Applegate, J. S. (2002). The taming of the precautionary principle. Wm. & Mary Envtl. L. & Pol'y Rev., 27, 13.
[568] Applegate, J. S. (2002). The taming of the precautionary principle. Wm. & Mary Envtl. L. & Pol'y Rev., 27, 13.
[569] Principle 15, Declaration, R. (1992). Rio declaration on environment and development.
[570] EC. Communication from the Commission on the Precautionary Principle. Brussels: Commission of the European Communities, 2000.
[571] EC. Communication from the Commission on the Precautionary Principle. Brussels: Commission of the European Communities, 2000.
[572] Ahteensuu, M. (2007). Defending the precautionary principle against three criticisms. Trames, 11(4), 366-381.

more science before establishing regulations that may get entrenched and difficult to course correct.[573] Furthermore, it lends flexibility to regulators whilst establishing a common standard to base situation -specific decisions upon.[574] More specifically, it makes the scientific discourse around risk management more intellectually honest by reframing the questions asked, highlighting underlying assumptions and making the risk analysis dynamic.[575]

Additionally, its proponents have also identified its contributions towards making the regulatory process itself more inclusive and transparent. The precautionary principle serves as a way to support democratic and transparent risk-related policies, in which a wide range of disciplines and stakeholders are equally welcomed to participate in the policy making process.[576] As will be seen in the section answering the research questions, these intended value additions seem to be highly exaggerated and cannot be seen to have occurred in the case of glyphosate authorization.

- ***Criticism***

On the other hand, it has also garnered a fair share of criticism since its promulgation. The primary accusation levelled against it is that of marginalizing scientific decision-making[577] in that it allows for greater credence to be given to perceptions rather than objective tests.[578] Furthermore, its inherently subjective nature makes any guidance it could have provided redundant- as the decision -makers still have no practical guidance as to what its operationalization precisely entails.[579]

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[573] Joel Tickner, Carolyn Raffensperger, The politics of precaution in the United States and the European union, Global Environmental Change, Volume 11, Issue 2, (2001), 175-180.
[574] Sadeleer, N. D. (2006). The precautionary principle in EC health and environmental law. European Law Journal, 12(2), 139-172.
[575] Gee, D., MacGarvin, M., Stirling, A., Keys, J., Wynne, B., & Vaz, S. G. (2001). Late lessons from early warnings: the precautionary principle 1896-2000. P. Harremoës (Ed.). Luxembourg: Office for Official Publications of the European Communities.
[576] Wibisana, M. R. A. G... "Law and economic analysis of the precautionary principle." Desertasi Doktor Maastricht University, Maastricht (2008).
[577] Chapman, P. M. (1999). Does the precautionary principle have a role in ecological risk assessment? Human and Ecological Risk Assessment: An International Journal, 5(5), 885-888;886.
[578] Sanderson, H., & Petersen, S. (2002). Power analysis as a reflexive scientific tool for interpretation and implementation of the precautionary principle in the European Union. Environmental Science and Pollution Research, 9(4), 221-226.
[579] Sunstein, C. R. (2005). The precautionary principle as a basis for decision making. The Economists' Voice, 2(2).

Compounding the problems is the view that this vagueness and subjectivity of the principle exposes regulatory processes to greater political discretion and non-scientific influence. In particular, it could lead to ignoring risk/risk trade-offs by decision-makers, as only a subset of relevant effects of a precautionary action are 'on-screen'.[580]

Another obvious adverse impact of the principle would be excessive precaution leading to a risk-averse bureaucracy and consequently, a technological stand-still.[581] This could result from either excessive costs to prove the safety of an activity or product discouraging innovators or excessive limitations being exercised by bureaucrats due to fear of public censure.

Lastly, the precautionary principle has the potential to enable regulatory overreach. As it is seen as protecting from serious threats, the public at large would be more amenable to unquestioningly accept regulatory action.[582]

7.2.2 Research questions

The discussion around the precautionary principle in the past 30 years has centered around the themes of the additional values and possible pitfalls, with each side further strengthening its arguments by deeper theoretical analysis using varied jurisprudential principles as also tenets of law and economics, game theory, public choice, and behavioral economics. A literature review of the field revealed the basic arguments put forth by its proponents and detractors as described in the earlier section. However, these arguments remain in the realm of theoretical speculation.

Hence, I found it meaningful and relevant to question if these theories have played out in the operationalization of the precautionary principle. To begin with, determining if there was value-addition to decision- making was difficult as it was not clear if the precautionary principle had been relied on in reaching decisions regarding uncertain threats. It must be acknowledged that even if explicit reliance is not placed on the principle, it could nevertheless play a role in shaping a decision, resulting in a different outcome than what a

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[580] Sunstein, C. R. (2005). Laws of fear: Beyond the precautionary principle (Vol. 6). Cambridge University Press.

[581] Nollkaemper, A. (1996). What you risk reveals what you value, and other dilemmas encountered in the legal assaults on risks. The Precautionary Principle and International Law: The Challenge of Implementation. Kluwer Law International, The Hague, 73-94; Miller, H. I., & Conko, G. P. (2004). The Frankenfood myth: how protest and politics threaten the biotech revolution. Greenwood Publishing Group, p. 96.

[582] Furedi, F. (2007). The only thing we have to fear is the 'culture of fear 'itself. American Journal of Sociology, 32, 231-234.

standard risk analysis would yield. Accordingly, the primary research question of the thesis was:

- What role does the precautionary principle play in decisions regarding uncertain threats?

In answering this question, three aspects can be considered, *viz:*

  - Is the precautionary principle explicitly relied upon in decisions regarding uncertain threats?
  - Does the precautionary principle have an implied value-addition to the decision-making process regarding uncertain threats?
  - Do the criticisms of the precautionary principle impact the decision-making process regarding uncertain threats?

To answer this question, the instance of glyphosate authorization in the EU was studied. The case was identified as suitable for invoking the precautionary principle due to scientific uncertainty concerning its threat to human health. Additionally, the importance of glyphosates for maintaining food supplies meant that limiting its use could not be a simple decision. Lastly, EU pesticide regulation allowed for varied decision-making at the EU and national levels. Thus, the decision could be studied for the three research questions at different administrative levels.

7.3 Answering the research questions

The analysis of decisions and policy relating to glyphosates elicits answers to the questions set forth earlier – both as regards the role of the precautionary principle in decision-making and also its role in shaping the regulatory process related to risk and uncertainty analysis.

7.3.1 No explicit reliance on the precautionary principle by decision-makers

A strong formulation of the precautionary principle would have meant that there be an outright rejection of glyphosate use. Neither at the EU level nor at any of the Member State level was there a strong formulation of the precautionary principle. An explicit reliance on the precautionary principle was not made by any of the legislative or executive bodies. Indeed, even though precaution permeates the risk analysis framework in pesticide regulation, in the case of glyphosate, divergent scientific opinions did not naturally lead to the adoption of a more cautious or risk-averse response.

Throughout the discussions relating to glyphosate reauthorization, the only instances in which arguments explicitly relying on the precautionary principle were advanced were in public consultations and in judicial cases.[583]Even in judicial decisions, the principle was discussed if it was raised by the party seeking limitations on glyphosate use. The judiciary itself did not seek to base its decisions on the precautionary principle, if not pleaded by the applicant.

Thus, it is striking that no governmental agency or decision-making body has relied on the precautionary principle in spite of legal provisions allowing and, in some cases, requiring the use of the precautionary principle.

Even in the realm of shaping regulatory processes in relation to glyphosate authorization, the precautionary principle has not played any significant role. As a whole, the very public and contentious nature of the issue at hand did result in a more transparent and multi-disciplinary risk analysis. However, all the measures resulting in a more democratic regulatory process were rooted in existing frameworks for better regulation and risk management in the EU. [584] The public outcry merely resulted in a more fastidious compliance with the existing frameworks. The precautionary principle was not required to bring about a change in the process or outcome.

Even when comparing the glyphosate policy and regulations at the national level, an explicit reliance on the precautionary principle is seen only in a very specific case of France. In fact, in this country, the reliance on the precautionary principle even led to potential regulatory overreach at the municipal level, albeit it was swiftly deemed unconstitutional. In the Netherlands there was no explicit reliance on the precautionary principle; the prevalent risk analysis framework was applied. The case of Germany was specific in the sense that the ultimate approval of glyphosates at the EU level resulted from the exercise of individual discretion by the then German agricultural minister. This, however, led to such a backlash against this unilateral decision, that it pushed the German government at the national level to

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[583] Barbara Cassasus, *French court bans sale of controversial weedkiller,* NATURE, 24 January 2019. Available at :https://www.nature.com/articles/d41586-019-00259-x#:~:text=France%20is%20among%20the%20nations,fierce%20arguments%20between%20member%20states. Last accessed 10 May 2022.; Robert Kunzig, *Bavarians vote to save bugs and birds—and change farming,* National Geographic, 13 February 2019. Available at: https://www.nationalgeographic.com/environment/article/bavarians-vote-save-bugs-birds-change-farming Last accessed 10 May 2020.

[584] Vermeire, T. G., & van Leeuwen, C. J. (Eds.). (2007). Risk Assessment of Chemicals: An Introduction. Springer, 7.

introduce legislation to phase out glyphosates (although it had approved glyphosates at the EU level). However, this German domestic legislation leading to the phase out of glyphosates also did not explicitly rely on the precautionary principle. The ban was, moreover, a deviation from the applicable German pesticide policy as that would at best have suggested to apply safety measures and monitoring the frequency of the use. Summarizing, even though some precautionary measures against glyphosates were adopted in all three countries examined (France, Germany and the Netherlands), those measures were not explicitly based on the precautionary principle.

Despite uncertainty and divergent scientific opinions, the precautionary principle appears to have played at best a minimal role in the decision-making. The principle remains a catchword to rally public opinion but does not find a place in administrative decision-making. An important consideration for further research might be the reframing of the aim and operation of the precautionary principle.

7.3.2 Limited value-addition of the precautionary principle

Aside from the over-arching decision regarding authorization of use, there were different opportunities for regulating the threat to varied extents. Almost all Member-States availed of these opportunities, irrespective of their stance at the EU level. Thus, it casts doubt on whether the decision at the EU level was informed solely by risk analysis. It is also interesting to understand how a threat might be regulated differently if it is viewed as far removed due to the administrative level of the decision-making body where it is discussed.

Most of these limiting measures at the national level were introduced independently and at a later moment, even after the risk management decisions of the national authorities, even if the risk management framework allowed for control measures. Many times, these measures were introduced as response to concerns raised in public referenda- as in the case of Germany. Even though there was still no explicit reliance on the precautionary principle, some of the language instituting these measures did mirror the language used to define the precautionary principle. The most striking example of this would be the ANSES (France) reversing the burden of proof as to the benign nature of glyphosate-containing products.

Thus, it would be erroneous to say that the precautionary principle had absolutely no role to play in the response to the uncertain threat. It provided the language, firstly to make the uncertainty caused by the divergent scientific opinions more salient; and secondly, for the adaptable measures suited to the specific concerns of the different member-states.

Nevertheless, it was a limited role and still cannot be seen adding value to the decision-making or the regulatory process itself.

7.3.3 Decision-making in the case of glyphosates does not exhibit the criticisms of the precautionary principle

As suggested by critics of the precautionary principle, there is a greater risk-aversion to uncertain threats[585] , as is evident from the consistent public opposition and distrust in decisions and scientific reports of the authorizing agencies. However, in all instances, precautionary regulations have been measured and simultaneously sought to mitigate any adverse impacts the regulation may have on other areas. Thus, even if there may be an exaggerated view of the threat in the public, it has not caused administrative decisions to ignore the risk/risk trade-off. Neither has it resulted in a risk-averse bureaucracy. Rather than stagnate innovation, public outcry has resulted in opening up new avenues of research. It is significant to see that perhaps the bureaucracy is less fearful of public censure when regulating uncertain threats as compared to risks.

7.3.4 Adverse impacts of the precautionary principle seen only at the municipal level

There is not a complete absence of shortcomings resulting from the precautionary principle. The principle was relied on by different local municipal units to attempt to institute measures beyond their competencies. Strikingly these over-reaching measures garnered support from a majority of the citizens affected by it. Thus, there seems to be merit to the argument that the precautionary principle could be used as a trust-enhancing tool to enable regulatory over-reach. However, this can be observed only at the municipal level and is short-lived. Eventually, the over-reach gets corrected by way of judicial review or objections from minority groups. Nevertheless, it is worth considering restricting the level of the administrative agency that can rely on the precautionary principle as a justification for regulatory measures.

7.4 Implications and Suggestions

In light of the answers above, it can be seen that in this case the precautionary principle in its current formulation played a very limited role in decision-making, whether positive or

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[585] Adler, J. H. (2011). The problems with precaution: A principle without principle; Majone, G. (2002). The precautionary principle and its policy implications. JCMS: Journal of Common Market Studies, 40(1), 89-109; Sunstein, C. R. (2005). Laws of fear: Beyond the precautionary principle (Vol. 6). Cambridge University Press, 7.

negative. Even if it is a single case-study, it involves multiple decisions taken at different levels of government and by various agencies. In most of these decisions, the process and the outcomes remained the products of established risk analysis frameworks, and the precautionary principle had almost no role to play in them. It would suggest that uncertain threats are still being assessed based on risk analysis frameworks intended for certain risks. The distinction between uncertainty and risk sought to be made by the precautionary principle has not materialized. Thus, the gap regarding uncertain threats remains unaddressed- leaving open the question of what could be used if not the precautionary principle. Here, I would suggest that rather than reject the precautionary principle altogether, it would be better to reformulate its application. Considering the precautionary principle is seen to have a negative impact only in limited instances, it may still be worthwhile to reformulate the principle or to articulate its operationalization better to address this failing in the risk regulatory framework.

More specifically, it would be beneficial to rethink the action dimension of any principle purporting to address uncertainty. A principle with an action dimension requiring and guiding better understanding of the uncertainty rather than claiming to help directly with decision-making could actually be a valuable addition to the current assessment frameworks. The inherently subjective choices made during the ostensibly objective risk assessment stage were made salient by a more nuanced consideration of the divergent risk assessments. Consequently, countervailing measures based on differences in those choices could be suggested and implemented, going beyond the binary of authorization or rejection.

The incompleteness of the CBA mentioned in earlier chapters comes from inability to have complete information in certain situations. With the advent of big data and increasingly more information, it would seem that the instances of these situations would reduce. However, as can be seen in this case, even with means to information and testing, credible scientific divergence can persist. Thus, it is not sufficient to just supplement a CBA with more information to address the issue. In this regard, the suggested reframed application of the precautionary principle would be helpful. The principle would then not affect the authorization decision of a product/ technology but rather the ancillary research and the communication of the risk.

Another consideration worth exploring is the possible added value that the precautionary principle could bring to risk communication. In the instant case even if the principle was not

used to this end, it did provide standing and the language for stakeholders to convey their concerns to the risk managers. At the same time the elaboration of scientific divergence required by the principle also would result in a more nuanced communication from the risk assessors to the managers. In effect, the gap between those most likely affected by the risk, those with the least cost to access information about the risk, and those with the most control over the management of the risk can be reduced if the operationalization of the precautionary principle is reworked to purposefully include this as an objective of the principle. Consequently, the decisions about uncertain risk can then be better shouldered by these groups.

In sum, it appears that the precautionary principle in its present form has not played a role in the case of glyphosates, even if it was legally applicable. Thus, neither is it adding the purported value to decision-making nor is it causing the speculated innovation standstill. At this stage, it might be a case of throwing the baby out with the bath water to outright reject the precautionary principle. It might still be useful in limited cases where no information is available. Further, in cases where divergence/ uncertainty persists despite availability of information, the adjusted functions of the principle relating to communication and interpretation of information would be useful.

These conclusions are partially in a similar vein to those put forth in the '*Guidance on application of the precautionary principle in the EU'*[586] published as the result of the RECIPES (REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders) project.[587] The RECIPES project suggests that the precautionary principle can fulfil a dual role of a legal safeguard(allowing early interventions in case of uncertainty) and a compass(stimulating upstream debates and research about the potential impacts of emerging technologies and related innovation pathways). The analysis of the glyphosate response in this thesis points to the second role of being a compass as a more realistic value addition. The role of the legal safeguard has been long acknowledged within the EU- nevertheless, it did not add to the decision-making process for glyphosate authorization. As such, it is more meaningful to focus on the second role as compass and better articulate its

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[586] Oldervoll, J. A., Asenova, D., Dimova, A., Dreyer, M., Drivdal, L. E., Schweizer, P. J., ... & Tjelle Holm, N. K. (2022). WP3, Deliverable 3.2 Guidance on the application of the precautionary principle in the EU.
[587] Joe Rini (IASS Potsdam) WP2 Conceptual framework for comparative multiple case study analysis, December 4, 2019. The RECIPES project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824665

operationalization to fulfil this role. This role of a compass can also be expanded to help guide public discourse and risk communication.

On a different note, this analysis also sheds light on how the same government might regulate the same uncertainty differently depending on the administrative unit where the regulation is being promulgated. Further research in this area could have implications for behavioral sciences in understanding risk perception as well as for the division of regulatory powers with respect to risk in federal systems.

Lastly, apart from explaining the actual working of the precautionary principle in regulatory decisions, the thesis could also serve as a framework for further positive analysis of the precautionary principle's role in regulating other uncertain serious threats to the environment or human health.

APPENDIX

Classification schemes of EU and IARC as regards carcinogenicity explained

Source : Tarazona, J. V., Tiramani, M., Reich, H., Pfeil, R., Istace, F., & Crivellente, F. (2017). Glyphosate toxicity and carcinogenicity: a review of the scientific basis of the European Union assessment and its differences with IARC. *Archives of toxicology*, *91*(8), 2723-2743.

EU SCHEME BASED ON UN GUIDELINES

Category 1A	Category 1B	Category2	No classification
Substances known to have carcinogenic potential for humans Largely based on human evidence	Substances presumed to have carcinogenic potential for humans Largely based on animal evidence	Substances suspected to have carcinogenic potential for humans Evidence obtained from human and/or animal studies but not sufficiently convincing to place the Substance in Category 1A or 1B	No sufficient evidence for classifying the substance as carcinogenic

IARC SCHEME

Group 1	Group 2A	Group 2B	Group 3	Group 4
The agent is a carcinogen for humans. This category is only used when sufficient indications of carcinogenicity for humans are available.	The agent is probably carcinogenic for humans. The classification of an agent into this category is recommended if there is no formal evidence of carcinogenicity in humans, but corroborating indicators of its carcinogenicity for humans and sufficient evidence of carcinogenicity in experimental animals.	The agent is possibly carcinogenic for humans. There is limited evidence of carcinogenicity in humans and evidence for animals, or insufficient evidence for human beings but sufficient evidence of carcinogenicity in experimental animals	Agent not classifiable as to its carcinogenicity to humans. (Insufficient evidence for human beings and insufficient or limited for animals)	Agent probably not carcinogenic for humans (Evidence suggesting lack of carcinogenicity in humans and in experimental animals)

References

Books

Backhaus, J. (eds) *Encyclopedia of Law and Economics*. Springer, New York, NY. https://doi.org/10.1007/978-1-4614-7883-6_124-1

Cranor, C. F. (2016). *Toxic torts*. Cambridge University Press.

De Sadeleer, N. (2014). *EU environmental law and the internal market,* OUP Oxford.

Deville, A., & Harding, R. (1997). *Applying the precautionary principle*. Federation Press.

E. Bozzini, (2017). *Pesticide Policy and Politics in the European Union: Regulatory Assessment, Implementation and Enforcement,* Palgrave Macmillan.

Fisher, E. C. (2007). *Risk regulation and administrative constitutionalism*, Bloomsbury Publishing.

L. Kramer (2016). *EU Environmental Law*, 8th Ed Sweet & Maxwell.

Mueller, D. C. (2003). *Public choice III*, Cambridge University Press

O'Riordan, T. (2013). *Interpreting the precautionary principle,* Routledge.

Rowley C.K., Schneider F. (eds) *The Encyclopedia of Public Choice.* Springer, Boston, MA, 671.

Saracci, R. (2016). *Old and New Risks: Challenges for Environmental Epidemiology,* EHP Publishing.

Shavell, S. (1987). *Economic Analysis of Accident Law*, London: Harvard University Press.

Sunstein, C. R. (2005). *Laws of fear: Beyond the precautionary principle (Vol. 6),* Cambridge University Press.

Hey, E., & Freestone, D. (1995). *The precautionary principle and international law: the challenge of implementation*, The Hague: Wolters Kluwer.

Vermeire, T. G., & van Leeuwen, C. J. (Eds.). (2007). *Risk Assessment of Chemicals: An Introduction*, Springer.

Wibisana, M. R. A. G., and Andri Gunawan. "*Law and economic analysis of the precautionary principle*." Desertasi Doktor Maastricht University, Maastricht (2008).

Yin, Robert, K. (2018). '*Case Study Research: Design and Methods'*, Sage Publications Ltd.; 6th edition.

Articles

Adler, J. H. (2011). The problems with precaution: A principle without principle.

Aerni, P. (2019). Politicizing the Precautionary Principle: why disregarding facts should not pass for farsightedness. *Frontiers in plant science*, *10*, 1053.

Ahteensuu, M. (2007). Defending the precautionary principle against three criticisms. *Trames*, *11*(4), 366-381.

Antier, C., Andersson, R., Auskalniene, O., Barić, K., & Simić, M. (2020). A survey on the uses of glyphosate in European countries. *ENDURE network*, 1-60.

Applegate, J. S. (2002). The taming of the precautionary principle. *Wm. & Mary Envtl. L. & Pol'y Rev*., 27, 13.

Arrow, K.J. and A. Fisher. 1974. "Environmental Preservation, Uncertainty, and Irreversibility". *The Quarterly Journal of Economics*, Vol. 88, Issue 2, May, pp. 312-319.

Beck, U. (1996). Risk society and the provident state. *Risk, environment and modernity: Towards a new ecology*, *31*, 29-43.

Benbrook, C. M. (2016). Trends in glyphosate herbicide use in the United States and globally. *Environ. Sci. Eur.* 28:3. doi: 10.1186/s12302-016-0070-0

Berger, G., Graef, F., Pallut, B., Hoffmann, J., Brühl, C. A., and Wagner, N. (2018). How does changing pesticide usage over time affect migrating amphibians: a case study on the use of glyphosate-based herbicides in German agriculture over 20 years. *Front. Environ. Sci.* 6:6.

Bodansky, D. (1991). Law: scientific uncertainty and the precautionary principle. *Environment: Science and Policy for Sustainable Development*, *33*(7), 4-44.

Bonny, S. (2011). Herbicide-tolerant transgenic soybean over 15 years of cultivation: pesticide use, weed resistance, and some economic issues. Case of the USA. *Sustainability* 3, 1302–1322.

Brickman, R., & Jasanoff, S. (1985). Iglen T. Controlling chemicals: the politics of regulation in Europe and the United States. Ithaca; Fisher, E. (2014). Chemicals as Regulatory Objects. *Review of European, Comparative & International Environmental Law*, *23*(2), 163-171.

Bürger, Jana, Friederike de Mol, and Bärbel Gerowitt. "The "necessary extent" of pesticide use—thoughts about a key term in German pesticide policy." *Crop Protection* 27.3-5 (2008): 343-351.

Butler, E. (2012). Public choice-a primer. *Institute of Economic Affairs Occasional Paper*, *147*.

Cass R. Sunstein, Beyond the Precautionary Principle, 151 U. PA. L. REV. 1003, 1024 (2003).

Chapman, P. M. (1999). Does the precautionary principle have a role in ecological risk assessment? *Human and Ecological Risk Assessment: An International Journal*, *5*(5), 885-888.

Charnley, G. (2000). 1999 Annual Meeting. Past President's Message: Risk Analysis under Fire. *RISK newsletter*, *20*(3).

Dana, D. (2009). The Contextual Rationality of the Precautionary Principle. *Queen's LJ*, *35*, 67.

De Jong, F. M., De Snoo, G. R., & Loorij, T. P. (2001). Trends of pesticide use in The Netherlands. *Mededelingen (Rijksuniversiteit te Gent. Fakulteit van de Landbouwkundige en Toegepaste Biologische Wetenschappen)*, *66*(2b), 823–834.

Dill, G. M., Sammons, R. D., Feng, P. C. C., Kohn, F., Kretzmer, K., Mehrsheikh, A., et al. (2010). "Glyphosate: discovery, development, applications, and properties," in Glyphosate Resistance in Crops and Weeds: History, Development, and Management. ed V. K. Nandula (Hoboken, NJ: Wiley), 1–33.

Eckley, Noelle and Selin, Henrik, "All talk, little action: precaution and European chemicals regulation", 11 *Journal of European Public Policy* (2004), pp. 78.

Farber, D. A. (2015). Coping with Uncertainty: Cost-Benefit Analysis, The Precautionary Principle, and Climate Change, 90 Wash. *L. Rev*, *1659*, 1694-95.

Fisher, E. (2008). The 'perfect storm' of REACH: charting regulatory controversy in the age of information, sustainable development, and globalization. Journal of risk research, 11(4), 541-563, 542.

Fisher, E. (2013). Framing risk regulation: A critical reflection. *European Journal of Risk Regulation*, *4*(2), 125-132, 127.

Fon, V., & Parisi, F. (2007). On the optimal specificity of legal rules. *Journal of Institutional Economics*, *3*(2), 147-164.

Foucart, S., and Horel, S. (2018). Food safety: risk of glyphosate flagged. *Nature* 555,443.

Furedi, F. (2007). The only thing we have to fear is the 'culture of fear'itself. *American Journal of Sociology*, *32*, 231-234.

Gardiner, S. M. (2006). A core precautionary principle. *Journal of Political Philosophy*, *14*(1).

Garnett, K. and Parsons, D.J. (2017), Multi-Case Review of the Application of the Precautionary Principle in European Union Law and Case Law. *Risk Analysis*, 37: 502-516, 502. https://doi.org/10.1111/risa.12633

Gee, D., MacGarvin, M., Stirling, A., Keys, J., Wynne, B., & Vaz, S. G. (2001). *Late lessons from early warnings: the precautionary principle 1896-2000*. P. Harremoës (Ed.). Luxembourg: Office for Official Publications of the European Communities.

Geistfeld, M. (2001). Implementing the precautionary principle. *Environmental Law Reporter*, 31.

Gillezeau, C., van Gerwen, M., Shaffer, R. M., Rana, I., Zhang, L., Sheppard, L., & Taioli, E. (2019). The evidence of human exposure to glyphosate: a review. *Environmental Health*, *18*(1), 1-14.

Godard, O. (2012). The Precautionary Principle and chemical risks. *The Philosophy of Chemistry: Practices, Methodologies, and Concepts*, 65-96.

Gollier, C.; B. Jullien; and N. Treich. 2000. "Scientific Progress and Irreversibility: An Economic Interpretation of the 'Precautionary Principle'". *Journal of Public Economics*, Vol. 75, pp. No. 2, pp. 229-253

Graham, J. D., & Wiener, J. B. (2008). The precautionary principle and risk–risk trade-offs: a comment. *Journal of Risk Research*, *11*(4), 465-474.

Grandjean, P., Bailar, J. C., Gee, D., Needleman, H. L., Ozonoff, D. M., Richter, E.,…Soskolne, C. L. (2004). Implications of the Precautionary Principle in research and policy-making. *American Journal of Industrial Medicine*, 45(4), 382–385. https://doi.org/10.1002/AJIM.10361

Hansen, S. F., von Krauss, M. K., & Tickner, J. A. (2008). The precautionary principle and risk-risk trade-offs. *Journal of Risk Research*, *11*(4), 423-464.

Hansson, S. O. 1997. The Limits of Precaution. *Foundations of Science* 2, 293–306.

Heyvaert, V. (2006). Facing the consequences of the precautionary principle in European Community law. *European Law Review*, *31*(2), 185

Heyvaert, V. (2006). Guidance without constraint: assessing the impact of the precautionary principle on the European Community's chemicals policy, *Yearbook of European environmental law*, 6.

Jiang, P. (2014). A uniform precautionary principle under EU law. Peking U. Transnat'l L. Rev., 2, 490.

Kaplow, L. (1992). “Rules versus standards, an economic analysis.” *Duke Law Journal*, 557–629.

Kempenaar, C., & Spijker, J. H. (2004). Weed control on hard surfaces in The Netherlands. *Pest Management Science: formerly Pesticide Science*, *60*(6), 595-599.

Klika, C. (2015). Risk and the Precautionary Principle in the Implementation of REACH: The Inclusion of Substances of Very High Concern in the Candidate List. *European Journal of Risk Regulation*, *6*(1), 111-120

Knight, F. H. (1971). Risk, uncertainty and profit, 1921. *Library of Economics and Liberty*.

Kolstad, C.D; T. S. Ulen; and G.V. Johnson. 1990. “Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes of Complements?”. The American Economic Review, Vol. 80, No. 4, pp. 888-901.

Kristoffersen, P., Rask, A. M., Grundy, A. C., Franzen, I., Kempenaar, C., Raisio, J., ... & Zarina, L. (2008). A review of pesticide policies and regulations for urban amenity areas in seven European countries. *Weed Research*, *48*(3), 201-214, 208.https://doi.org/10.1111/j.1365-3180.2008.00619.x

Kuntz-Duriseti, K. 2004. “Evaluating the Economic Value of the Precautionary Principle: Using Cost-benefit Analysis to Place a Value on Precaution”. Environmental Science and Policy, Vol. 7, No. 4, August, pp. 291-301.

Lamichhane, Jay Ram, Antoine Messéan, and Pierre Ricci. "Research and innovation priorities as defined by the Ecophyto plan to address current crop protection transformation challenges in France." *Advances in agronomy* 154 (2019): 81-152.

Lenaerts, K. (2004). “In the Union we trust”: Trust-enhancing principles of Community law. *Common Market Law Review*, 41(2), 317-343.

Löfstedt RE. The precautionary principle in the EU: Why a formal review is long overdue. *Risk Management*, 2014; **16**(3): 137–163;

Lofstedt, R. E. (2003). The precautionary principle: Risk, regulation and politics. *Process Safety and Environmental Protection*, *81*(1), 36-43.

Majone, G. (2002). The precautionary principle and its policy implications. JCMS: *Journal of Common Market Studies*, 40(1), 89-109

McHenry, Leemon B. "The Monsanto Papers: poisoning the scientific well." *International Journal of Risk & Safety in Medicine* 29.3-4 (2018): 193-205.

Meyer, C. B. (2001). A case in case study methodology. Field Methods, 13(4), 329- 352, 333.

Michael D. Rogers (2011) Risk management and the record of the precautionary principle in EU case law, Journal of Risk Research, 14:4, 467-484, DOI: 10.1080/13669877.2010.547255;

Miller, H. I., & Conko, G. P. (2004). The Frankenfood myth: how protest and politics threaten the biotech revolution. Greenwood Publishing Group.

Morris, J. (2000). 'Defining the Precautionary Principle', in J. Morris (ed.) Rethinking Risk

Niskanen, W. A. (1968). The peculiar economics of bureaucracy. *The American Economic Review*, *58*(2), 293-305

Nollkaemper, A. (1996). What you risk reveals what you value, and other dilemmas encountered in the legal assaults on risks. *The Precautionary Principle and International Law: The Challenge of Implementation. Kluwer Law International, The Hague*, 73-94

Oldervoll, J. A., Asenova, D., Dimova, A., Dreyer, M., Drivdal, L. E., Schweizer, P. J., ... & Tjelle Holm, N. K. (2022). WP3, Deliverable 3.2 Guidance on the application of the precautionary principle in the EU.

Peter H. Sand (2000) The Precautionary Principle: A European Perspective, *Human and Ecological Risk Assessment: An International Journal*, 6:3, 445-458, DOI: 10.1080/10807030091124563

Portier, C. J., Armstrong, B. K., Baguley, B. C., Baur, X., Belyaev, I., Bellé, R., ... & Budnik, L. T. (2016). Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA). *J Epidemiol Community Health*, *70*(8), 741-745.

Purnhagen, K. (2014). The behavioural law and economics of the precautionary principle in the EU and its impact on internal market regulation. *Journal of consumer policy*, *37*(3), 453-464.

Raffensperger, C., & deFur, P. L. (1999). Implementing the precautionary principle: Rigorous science and solid ethics. *Human and Ecological Risk Assessment: An International Journal*, 5(5), 933-941.

Röttger-Wirtz, S. (2020). Case C-616/17 Blaise and Others: The precautionary principle and its role in judicial review–Glyphosate and the regulatory framework for pesticides. *Maastricht Journal of European and Comparative Law*, *27*(4), 529-542.

Sadeleer, N. D. (2006). The precautionary principle in EC health and environmental law. *European Law Journal*, *12*(2), 139-172.

Sanderson, H., & Petersen, S. (2002). Power analysis as a reflexive scientific tool for interpretation and implementation of the precautionary principle in the European Union. *Environmental Science and Pollution Research*, *9*(4), 221-226.

Sandin, P. (1999). Dimensions of the precautionary principle. *Human and Ecological Risk Assessment: An International Journal*, 5(5), 889-907.

Sandin, P., Peterson, M., Hansson, S. O., Rudén, C., & Juthe, A. (2002). Five charges against the precautionary principle. *Journal of Risk Research*, 5(4), 287-299.

Schebesta, H. (2022). Juridisch onderzoek glyfosaathoudende gewasbeschermingsmiddelen. *Wageningen Universty & Research.*

Schummer, J. (2001). Ethics of chemical synthesis. *HYLE–International Journal for Philosophy of Chemistry*, *7*(2), 103-124, 111.

Stigler, G. (1971). The economic theory of regulation. *Bell Journal of Economics*, *2*(1), 3-21

Stokes, E. (2008). The EC courts' contribution to refining the parameters of precaution. *Journal of Risk Research*, *11*(4), 491-507

Sunstein, C. R. (2005). The precautionary principle as a basis for decision making. *The Economists' Voice*, *2*(2).

Székács, A., & Darvas, B. (2018). Re-registration challenges of glyphosate in the European Union. *Frontiers in Environmental Science*, *6*, 78, 79.

Tarazona, J. V., Tiramani, M., Reich, H., Pfeil, R., Istace, F., & Crivellente, F. (2017). Glyphosate toxicity and carcinogenicity: a review of the scientific basis of the European Union assessment and its differences with IARC. *Archives of toxicology*, *91*(8), 2723-2743.

Tickner, J., & Raffensperger, C. (2001). The politics of precaution in the United States and the European Union. *Global Environmental Change*, *11*(2), 175-180.

Treich, N. (2001). What is the economic meaning of the precautionary principle? The Geneva Papers on Risk and Insurance. Issues and Practice, 26(3), 334-345.

Tullock, G. (1967). The welfare costs of tariffs, monopolies, and theft. *Economic inquiry*, *5*(3), 224-232.

Van Zwanenberg, P. and A. Stirling. 2003. "Risk and Precaution in the US and Europe: A Response to Vogel". In: Somsen, H., et al. (eds.). The Yearbook of European Environmental Law, Vol. 3. Oxford: Oxford University Press, pp. 43-56.

Vlek, C. (2009). A precautionary-principled approach towards uncertain risks: review and decision-theoretic elaboration. *Erasmus L. Rev.*, *2*, 129.

Von Schomberg, R. (2012) The precautionary principle: Its use within hard and soft law. *European Journal of Risk Regulation.* 2: 147–156.

Yan, H. (2020). Refining the Precautionary Principle in Public International Law. *US-China Law Review, 17*.

Zadoks, J. C. (1991). A hundred and more years of plant protection in the Netherlands. *Netherlands Journal of Plant Pathology*, *97*, 3-24.

Zyoud, S. H., Waring, W. S., Al-Jabi, S. W., and Sweileh, W. M. (2017). Global research production in glyphosate intoxication from 1978 to 2015: a bibliometric analysis. *Hum. Exp. Toxicol.* 36, 997–1006.

Laws and regulations

Decree of 5 September 2007, containing further rules regarding plant protection products and biocides (Plant Protection Products and Biocides Decree).

Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve a sustainable use of pesticides

Directive, W. F. (2003). Common implementation strategy for the water framework directive (2000/60/EC).

European Commission (1991). *Council Directive 91/414/EEC of 15 July 1991 Concerning the Placing of Plant Protection Products on the Market. OJ L230:1–32*.

European Commission (2010). *Commission Directive 2010/77/EU of 10 November 2010 amending Council Directive 91/414/EEC as Regards the Expiry Dates for Inclusion in Annex I of Certain Active Substances. OJ L293:48–57.*

European Commission (2011a). *Commission Implementing Regulation Renewing the Approval of the Active Substance Glyphosate In Accordance With Regulation (Ec) No 1107/2009 of the European Parliament and of the Council Concerning The Placing of Plant Protection Products on the Market and Amending The Annex to Implementing Regulation (Eu) No 540.*

European Commission (2011b). *Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L153:1–186*.

IARC Statute, Rules and Regulations - Fourteenth Edition, 2014 (modified Article 7.3 of IARC Financial Regulations and updated list of Participating States as at 15 May 2024) https://governance.iarc.who.int/documentation/statute-iarc.pdf

Law on the Establishment of a Federal Office for Consumer Protection and Food Safety (BVL Law - BVLG)

Ordinance on plant protection products and tools used in plant protection of 9 March 2005(BGBl. I n.53 p.2161-2169)

Plant Protection Act of February 6, 2012 (BGBl. I p. 148, 128)

Regeling van de Staatssecretaris van Economische Zaken van 7 december 2016, nr. WJZ/16152180, tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met aanpassing van het keuringsregime voor apparatuur.

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, *OJ L 31, 1.2.2002, p. 1–24.*

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

Wet gewasbeschermingsmiddelen en biociden, 2007.

World Health Organization. (2003). Financial regulations and financial rules. World Health Organization. https://iris.who.int/handle/10665/68539

Cases

Case C-673/13 P (Commission v Greenpeace Netherlands and PAN Europe).
Case C-180/96 P UK v Commission [1996] ECR I-3903
Case C-419/17P Deza [2019] C: 2019:52
Case T-13/99, Pfizer Animal Health SA v Council [2002] E.C.R. II-3305
Case T-199/96 Bergaderm [1998] ECR II-2805
Case T-451/13 Bayer [2018] T : 2018 :624
Case T-344 &T-345/00CEVA Santé Animale [2003]

Governmental publications

A Gides and AM Soto, 'Bisphenol A: contested science, divergent safety evaluations' in EEA Report No 1/2013 (Luxembourg, 2013).

Aarnink, W. H. B., van der Bolt, F. J. E., Merkelbach, R. C. M., & Westein, E. (1996). *Belasting van grond-en oppervlaktewater met bestrijdingsmiddelen in de stroomgebieden van de Beerze, Reusel en Rosep* (No. 456). DLO-Staring Centrum

Ashford, N., Barrett, K., Bernstein, A., Costanza, R., Costner, P., Cranor, C., ... & Warledo, J. (1998). *Wingspread statement on the precautionary principle.*

Autorisationdes produits phytopharmaceutiques, comment ça marche ? (2022). [Slide show]. INFOGRAPHIC MA AUTHORISATIONS, France. https://www.anses.fr/en/content/examining-marketing-authorisation-applications.

Bourguignon D., Authorisation of pesticides in the EU, EPRS, European Parliamentary,2018

Bourguignon D., EU policy and legislation on pesticides: Plant protection products and biocides, EPRS, European Parliament, 2017.

Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", December 2017 available at: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_.

Convenant Duurzaam Beheer (2001) *Zeeuwse overheden samen sterk bij het afbouwen van chemische onkruidbestrijding.* Provincie Zeeland, Middelburg, the Netherlands

De Wolf P., WUR/ Boerderij van de Toekomst (2023), Wetenschappelijke reflectie vanuit landbouwkundig perspectief Glyfosaat – een noodzakelijk kwaad? *Rondetafel Tweede Kamer 4-10-2023*.

EC. Communication from the Commission on the Precautionary Principle. Brussels: Commission of the European Communities, 2000.

EC. Conclusions of the presidency adopted at the end of the European Council in Nice on 8 December 2000. Annex III, Resolution on the precautionary principle. *Bulletin of the European Union*, 2000; **12**: 8–30

ELS study (Consumption study to determine the food intake of infants and young children for the estimation of an acute toxicity risk from pesticide residues, „Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von Pflanzenschutzmitteln"), 2002.

Ethical framework. (2022, January 17). Anses - Agence Nationale De Sécurité Sanitaire De L'alimentation, De L'environnement Et Du Travail. https://www.anses.fr/en/content/ethical-framework.

European Commision Press Memo, 'Questions & Answers: Commission replies to European Citizens' Initiative on Glyphosate and announces more transparency in scientific assessments', 12 December 2017 available at: https://ec.europa.eu/commission/presscorner/detail/en/MEMO_17_5192

European Commission (EC), Environment 2010: Our future, our choice - The Sixth Environmental Action Programme, COM (2001)31, Brussels 2002, http://europa.eu.int/comm/environment/newprg/

European Commission, Completing the Better Regulation Agenda: Better solutions for better results (2017), available at : https://ec.europa.eu/info/publications/completing-better-regulation-agenda-2017_en

European Commission, Glyphosates- facts and status. https://ec.europa.eu/food/plant/pesticides/glyphosate_en

European Court of Auditors, Management of conflict of interest in selected EU Agencies, Special Report No 15/2012, 11.10.2012.

European Food Safety Authority (2015a). Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. *EFSA J.* 13:4302; European Food Safety Authority (2015c). Request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine. *EFSA J.* 13:4303.

European Parliament Council (2002). *Laying down the General Principles and Requirements of Food Law, establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety. 178/2002/EC Regulation. OJ L031*. Available online at: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:en:PDF

German Federal Institute for Risk Assessment. Federal Institute for Risk Assessment (bfr) - Guidance Document for Health Assessments. *Zenodo*, 1 Nov. 2007, p., doi:10.5281/zenodo.580937.

Government policy. (n.d.). RIVM. https://www.rivm.nl/en/chemkap/fruit-and-vegetables/government-policy.Last

Hedda von Weddel, *Organisation des gesundheitlichen Verbraucherschutzes Schwerpunkt Lebensmittel,* (Schriftenreihe der Bundesbeauftragten für Wirtschaftlichkeit in der Verwaltung; Bd. 8) 8 February 2001.

IPCS. (2010). *WHO Recommended Classification of Pesticides by Hazard and Guidelines to Classification 2009*. World Health Organization.

Le Plan Ecophyto 2018, Ministère de l'agriculture et de l'alimentation (France), published 10 September 2008. Available at: https://agriculture.gouv.fr/ministere/le-plan-ecophyto-2018

Ministere de l'agriculture et de l'alimentation Communique, 27 July 2018. Available at: https://agriculture.gouv.fr/le-gouvernement-donne-une-nouvelle-impulsion-au-plan-ecophyto.

Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2017, September 28). *Mission, vision and strategy*. About the Ctgb | Board for the Authorisation of Plant Protection Products and Biocides. https://english.ctgb.nl/about-ctgb/mission-vision-and-strategy.

Ministerie van Landbouw, Natuur en Voedselkwaliteit. (2024, March 4). *Evaluation Manual v. 2024-1*. Assessment Framework PPP | Board for the Authorisation of Plant Protection Products and Biocides. https://english.ctgb.nl/plant-protection/documents/assessment-framework-ppp/2024/03/01/em-2024-1-march

MJPG-OG (Bestuurlijke afspraken uitvoering Meerjarenplan Gewasbescherming Openbaar Groen) (1997) *Ministerie van Landbouw, Natuurbeheer en Visserij, Ministerie van Ruimtelijke Ordening en Milieu, Ministerie van Verkeer en Waterstaat, Ministerie van Defensie, Ministerie van Volksgezondheid, Welzijn en Sport, Stichting GroenRaad, Vereniging van Nederlandse Gemeenten, NS/Railinfrabeheer, Unie van Waterschappen, Bosschap en Vereniging van samenwerkingsverbanden in de Openluchtrecreatie (OSO) (Covenant Implementation Multi Year Crop Protection Plan Urban Green)* (in Dutch).

PBL Netherlands Environmental Assessment Agency, & Ligtvoet, W. (2008). *Evaluation of the Water Framework Directive in the Netherlands; costs and benefits*. PBL Netherlands Environmental Assessment Agency.

Questions and Answers on Ensuring the Independence of the Federal Institute for Risk Assessment (BfR), Bundesamt fur Risikobewertung, 30 May 2012. Available at: https://www.bfr.bund.de/cm/349/questions-and-answers-on-ensuring-the-independence-of-the-federal-institute-for-risk-assessment.pdf

Reboud X. et al, 2017. Usages et alternatives au glyphosate dans l'agriculture française. Rapport Inra à la saisine Ref TR507024, 85 pages.

Science for Environment Policy (2017) The Precautionary Principle: decision making under uncertainty. Future Brief 18. Produced for the European Commission DG Environment by the Science Communication Unit, UWE, Bristol. Available at: http://ec.europa.eu/science-environment-policy

Sluijsmans, J. J. L., & Drijver, C. A. (1997). Terugdringen van het gebruik van chemische onkruidbestrijdingsmiddelen op verhardingen met behulp van detectie-spuittechniek (Reduction chemical weed control on pavements with sensor technology).

SPD, Bündnis 90/DIE GRÜNEN, Koalitionsvertrag 2002 - 2006: Erneuerung - Gerechtigkeit – Nachhaltigkeit, Berlin 2001

Special rapporteur on right to food- questionnaire to prepare annual report on the implications of the use of pesticides on the right to food Germany response, Permanent Mission of the Federal republic of Germany to the Office of the United Nations,30 November 2016.

Substance Glyphosate Prepared by the Rapporteur Member State Germany in the Framework of Regulation (EU) *No 1141/2010*.

United States Environmental Protection Agency (2015). *Evaluation of the Carcinogenic Potential of Glyphosate. Washington DC p. 1–87*. Available online at: https://www.acsh.org/wp-content/uploads/2016/05/EPA-glyphosate-document-final.pdf

Newspapers and online articles

Corporate Europe Observatory, PAN Germany and GLOBAL 2000, "Dangerous Confidence in 'Good Laboratory Practice'" (Corporate Europe Observatory, PAN Germany, and GLOBAL 2000, 2020) <https://www.global2000.at/sites/global/files/2020-GoodLaboratoryPractice-en.pdf>.

Ensie. (n.d.). Weet wat je eet - Geen gif op groente en fruit. Milieudefensie. *https://milieudefensie.nl/archief/weet-wat-je-eet-geen-gif-op-groente-en-fruit*.

Enter, M. (2022, October 11). *Glyphosate ban is possible - Resource online*. Resource Online. https://www.resource-online.nl/index.php/2022/10/10/glyphosate-ban-is-possible/?lang=en.

Germany, Pesticide Action Network. "Towards Pesticide Use Reduction in Germany." (2005)

National Action Plans, Integrated Pest Management and the Common. (2017, March 10). PAN Europe. *https://www.pan-europe.info/events/conferences/past-events-2005-2015/national-action-plans-integrated-pest-management-and-common*

REPORT: Water sampling confirms "closed" greenhouses leak an alarming. (2023, December 12). PAN Europe. https://www.pan-europe.info/press-releases/2023/12/report-water-sampling-confirms-%E2%80%9Cclosed%E2%80%9D-greenhouses-leak-alarming-number.

Stolstad, E. (2018, October 11). France's decade-old effort to slash pesticide use failed. Will a new attempt succeed? *science.org*.

2019/1 N. de Sadeleer, The PP and Management of Uncertainties in EU Law on Chemicals, published at http://desadeleer.eu.

Transparency Market Research (2014). Glyphosate Market for Genetically Modified and Conventional Crops - Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2013–2019. Albany: Transparency Market Research Available from: http://www.transparencymarketresearch.com/glyphosate-market.html

Dutchnews.nl

Euobserver.com

Euractiv.com

Guardian.com

https://www.pan-europe.info/press-releases

iarc.who.int

Inhabitant.com

Milieudefense.nl

Politico.eu

Resourceonline.nl

Reuters.com

Spiegel.de

Rfi.fr

Wur.nl/nl/nieuws

Summary

The thesis answers the question what role, if any, does the precautionary principle play in actual decision making when there is uncertainty regarding potential adverse effects to human health. In the about 30 years since its formulation in the Rio Declaration, there has been a rich academic discussion on whether the principle is actually needed as also its efficacy. Proponents and detractors have been equally active in understanding its potential impact on environmental decision-making. Proponents justify its use pointing to the inadequacy of a Cost Benefit Analysis to address irreversible serious threats whose probability of occurrence cannot be truly determined. Additionally, they claim that it allows to minimize regret, reallocate risk more efficiently and make regulatory process more inclusive and cognizant of the underlying assumptions of any risk analysis. On the other hand, critics argue that it is too vague to help and would rather cause a regulatory standstill. Moreover, it would also lead to risk-aversion/excessive precaution in the bureaucracy resulting in an innovation standstill ignoring risk/risk trade-offs.

The thesis uses the case of glyphosate authorization in the EU to understand if these theoretical arguments can be seen to occur in actual practice. The decision of authorization is studied at the EU level followed by a comparative case study of the national policy and regulation measures in France, Germany and the Netherlands. The case study shows that the precautionary principle has played a minimal role in its intended form in these decisions. It has neither added nor detracted from the decision-making. Additionally, though the risk gets assessed differently at the EU level and the national level, the precautionary principle is not relied on for adapting the regulations. The primary role played by the precautionary principle is to make public concerns more salient. However, very little impact is seen on the decision by the bureaucrat.

Consequently, the research is relevant as a starting point for reframing the precautionary principle. Furthermore, it helps understand the areas where the existing risk regulation frameworks would be sufficient and the gaps as yet unaddressed by them, despite the aid of the precautionary principle. Additionally, the difference between the EU level and the national legislations in the risk appetite regarding glyphosates are a relevant input for research in federalism.

Samenvatting

Het proefschrift geeft antwoord op de vraag welke rol het voorzorgsbeginsel speelt in de daadwerkelijke besluitvorming wanneer er onzekerheid bestaat over mogelijke nadelige effecten op de volksgezondheid. In de circa 30 jaar sinds de formulering ervan in de Rio-verklaring, is er een rijke academische discussie geweest over de vraag of het beginsel noodzakelijk is alsook doeltreffend. Voor- en tegenstanders hebben zich beide ingezet om de mogelijke impact ervan op de milieubesluitvorming te begrijpen. Voorstanders rechtvaardigen het gebruik van het beginsel door te wijzen op de ontoereikendheid van een kosten-batenanalyse om onomkeerbare, ernstige bedreigingen aan te pakken waarvan de waarschijnlijkheid niet zeker kan worden bepaald. Bovendien stellen zij dat het beginsel mogelijk maakt om spijt te minimaliseren, risico's efficiënter te herverdelen en het regelgevingsproces inclusiever en bewuster te maken van de onderliggende aannames van iedere risicoanalyse. Aan de andere kant beweren tegenstanders dat het beginsel te vaag is om te helpen en eerder zou leiden tot een regelgevingsimpasse. Bovendien zou het tot een risicomijdende of overdreven voorzichtige bureaucratie kunnen leiden, resulterend in een innovatie-impasse waarbij risico en risico-afwegingen worden genegeerd.

Het proefschrift onderzoekt of de theoretische argumenten omtrent het voorzorgsbeginsel zichtbaar zijn in de praktijk aan de hand van de casus van de toelating van glyfosaat binnen de EU. Het toelatingsbesluit wordt op EU-niveau bestudeerd, gevolgd door een vergelijkende casestudy van het nationale beleid en de regelgeving in Frankrijk, Duitsland en Nederland. Uit de casestudy blijkt dat het voorzorgsbeginsel in zijn beoogde vorm een minimale rol heeft gespeeld bij deze besluiten. Het heeft noch bijgedragen, noch afgedaan aan de besluitvorming. Daarnaast wordt, hoewel risico’s op EU- en nationaal niveau verschillend worden beoordeeld, het voorzorgsbeginsel niet ingeroepen voor het aanpassen van de regelgeving. De voornaamste rol van het voorzorgsbeginsel is het vergroten van de aandacht voor publieke zorgen. Echter, de impact ervan op beslissingen door bureaucraten blijkt zeer beperkt te zijn.

Het onderzoek is dan ook relevant als uitgangspunt voor het herformuleren van het voorzorgsbeginsel. Bovendien helpt het inzicht te verkrijgen in de gebieden waar de bestaande risicoregelsystemen toereikend zouden zijn, en de leemten die deze systemen nog niet hebben aangepakt, ondanks de ondersteuning van het voorzorgsbeginsel. Daarnaast vormen de verschillen tussen het EU-niveau en nationale wetgevingen omtrent

risicobereidheid ten aanzien van glyfosaat een relevante input voor onderzoek naar federalisme.

Doctoral Activities 2018/2023

COURSES		
Name of the course	***Venue***	***Time period***
Introduction to Statistics	Bologna University	October 2018
Introduction To European Competition Law	Bologna University	October 2018
Environmental and Resource Economics	Bologna University	October-November 2018
Experimental Economics-Topics	Bologna University	November-December 2018
Modelling Private Law	Bologna University	November-December 2018
Behavioral law and economics and enforcement mechanisms	Bologna University	January-February 2019
Game theory, behavior and the law	Bologna University	January-February 2019
Law and development	Bologna University	January-February 2019
Empirical Legal studies	Bologna University	May 2019
Scientific Methods for Sustainable Decision Making	Bologna University	April- June 2019
DAAD and EDLE Summer School of Law and Economics: Empirical L&E Economics of religion Experimental L&E	Hamburg University	8th-29th July 2019 (3 weeks)
Academic writing in English	Erasmus University, Rotterdam	September-November 2019
Academic Integrity and Responsible Research	Erasmus University, Rotterdam (Online, CANVA)	September 2019
Advanced Data Analysis	Erasmus University, Rotterdam	December 2019
Managing your PhD	Erasmus University, Rotterdam	October – November 2019
Advanced Empirical Methods: Research Design	Erasmus University, Rotterdam	17th-22nd February 2020
Scientific Poster Making	Erasmus University, Rotterdam	March 2020
Advanced Empirical Methods: Research Design (applied)	Erasmus University, Rotterdam	June 2020
Advanced Computational Methods (Data mining and network analysis)	Erasmus University, Rotterdam (online)	14th-16th December 2020

Communicate your Research	Erasmus University, Rotterdam (EGSL Online Course, CANVA)	June-September 2021
How to deal with procrastination in a PhD?	Erasmus University, Rotterdam (PhD psychologist group course)	November 2021-February 2022

Conferences, seminars, presentations and contributions to publications		
Description	***Venue/ Organizer***	***Date***
EDLE 3rd year seminar	Bologna University	10th November 2018
Italian Society of Law and Economics Annual Conference	Lecce University	14th -16th December 2018
Inaugural Lecture of the Master's degree in resource Economics and Sustainable Development, "Greening Economy, Graying Society"	Rimini University	21st November 2018
EMLE Midterm Meeting Conference	Hamburg University	14th-15th February 2019
Hamburg lecture series on law and economics	Institute of Law and Economics, Hamburg University	8 Wednesdays from April-June 2019
Summer school on researching and teaching law and economics	Hamburg University	24th -28th June 2019
Behavioral law and economics workshop	Hamburg University	1st-5th July 2019
BACT seminar on "YouTube vs. Netflix: an empirical analysis of consumer behaviour"	Erasmus University, Rotterdam	19th September 2019
BACT Seminar on 'More than the Money: Payoff-Irrelevant Terms in Relational Contracts'	Erasmus University, Rotterdam	31st October 2019
Inclusive Prosperity Lunch seminars	Erasmus University, Rotterdam (Initiative for Dynamics of Inclusive Prosperity)	7th November 2019 28th November 2019
BACT Seminar "The Virtuous Cycle of Property"	Erasmus University, Rotterdam	21st November 2019

2nd-year EDLE Seminar (presentation chapter)	**Erasmus University, Rotterdam**	**5th December 2019**
Workshop 'On the Crossroads of Law and Economics'	Erasmus University, Rotterdam	11th December 2019
BACT Seminar "Primary motives behind outsourcing legal rules"	Erasmus University, Rotterdam	12th December 2019
EMLE Midterm Meeting	Erasmus University, Rotterdam	14th-15th February 2020
Poster presentation	**Erasmus University, Rotterdam**	**3rd March 2020**
2nd-year EDLE Seminar (presentation chapter)	**Erasmus University, Rotterdam**	**12th March 2020**
Future of Law and Economics	Maastricht University (Online)	15th May 2020
Transparency in EU policymaking: The case of glyphosate	EURACTIV, Brussels (virtual conference)	4th June 2020
2nd-year EDLE Seminar (presentation chapter)	**Erasmus University, Rotterdam (Online)**	**12th June 2020**
BACT Seminar Rachlinski	Erasmus University, Rotterdam (Online)	25th June 2020
On the Crossroads of Law and Economics	Erasmus University, Rotterdam (Online)	30th June 2020
Hamburg lecture series on law and economics	Institute of Law and Economics, Hamburg University (ONLINE)	July 2020
EDLE 2nd year seminars	Erasmus University, Rotterdam (Online)	21st October 2020, 4th November 2020, 2nd December 2020
BACT Seminar COVID-19 Compliance	Erasmus University, Rotterdam (Online)	29th October 2020
3rd year EDLE Bologna Seminar (presentation chapter)	**Bologna University (online)**	**6th November 2020**
BACT Seminar (prof. Jeroen Luyten)	Erasmus University, Rotterdam (Online)	10th December 2020
EDLE 2nd year seminars	Erasmus University, Rotterdam (Online)	13th January 2021, 27th January 2021, 10th February 2021, 24th February 2021, 3rd

		March 2021,10th March 2021, 17th March 2021
BACT Seminar	Erasmus University, Rotterdam (online)	14th January 2021
BACT Seminar "The Effect of Land Titling on Conflicts"	Erasmus University, Rotterdam (online)	11th February 2021
Society for Risk Analysis Benelux conference "Risk-technology nexus"	Eindhoven (online)	16th March 2021
BACT seminar "Compensation and redress for damage"	Erasmus University, Rotterdam (online)	18th March 2021
Joint Seminar- Future of Law and Economics (presentation)	**Maastricht University (online)**	**25th-26th March 2021**
Euractiv Policy Dialogue: Farming talks-experience From the field	Brussels (online)	20th April 2021
2nd year EDLE Seminars	Erasmus University, Rotterdam (online)	14th September 2021, 5th October 2021,12th October 2021, 19th October 2021, 2nd November 2021, 9th November 2021, 7th December 2021
METRO Seminars	Maastricht University(online)	27th October 2021, 29th November 2021
EURACTIV policy dialogue- Can glyphosates play a role in achieving greater biodiversity?	Brussels (online)	4th November 2021
EDLE 3rd year Bologna Seminar	Bologna University (online)	19th November 2021
EDLE Spring Seminar (presentation)	**Erasmus University, Rotterdam (online)**	**24th May 2022**
Ministry of Economic Affairs and Climate Policy of the Netherlands and the Organisation for Economic Cooperation and Development, "*Conference on the role of the precautionary principle in the energy transition and on regulating the risks of hydrogen."*	The Hague	5th July 2023
Discussion and comments on article in Het Financieele Dagblad titled "Waarom zijn glyfosaat en pfas er nog?", published 17th November 2023	Online	November 2023
Pestizidverordnung - Was ist der deutsche Ansatz?	Virtual Conference (EURACTIV)	19th February 2024

Stellingen behorende bij het proefschrift van Mrinmayi Sameer Katdare

1. The precautionary principle, in its present form in the EU, played a negligible role in case of scientific divergence relating to the plant protection product glyphosate. Decision-makers continued to rely on previously established risk assessment frameworks without any added value resulting from the precautionary principle.
2. The theorized negative impacts of the precautionary principle did not affect decision making relating to plant protection products as regards glyphosates in the EU.
3. The precautionary principle can help make salient the assumptions underpinning the risk management decisions.
4. The few instances of governmental overreach enabled by precautionary principle were limited to municipal authorities and not observed at the national or supranational level. The criticism of possible governmental overreach enabled by the precautionary principle can be mitigated by allowing only national/supranational agencies to rely on the precautionary principle.
5. Within the EU, uncertainty regarding threats to the environment or human health are primarily dealt with in the same manner as risks. Decision-making tools recognizing the distinction between uncertainty and risk have to be made more clearly implementable.
6. Scientific divergence about the certainty of a threat can persist in spite of sufficient data and testing possibilities. Such divergence can result from differing assumptions regarding acceptable risk and exposure thresholds.
7. The behavior and stated concerns of political parties can be simultaneously different at the EU level and within the national borders.
8. Mistrust of regulatory agencies arising from apparent lapses in transparency and due process also influences public risk perception of a threat.
9. A higher order regulatory principle cannot simultaneously operate as an everyday decision-making framework. For either to be effective, they have to be formulated keeping in mind the intended nature of their application.
10. Environmental regulation will always have to consider a risk/risk trade-off. These tradeoffs should be stated explicitly in regulatory decisions.
11. *Doing something is a decision. Not doing anything is also a decision. Not taking a decision is also a decision, only that you are not the one making it.*